

1-31-90

Vol. 55

No. 21

federal register

Wednesday
January 31, 1990

United States
Government
Printing Office

SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for private use, \$300

SECOND CLASS NEWSPAPER

Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097-6326)

RECEIVED
JAN 10 1900

THE
LIBRARY
OF THE
MUSEUM
OF
COMPARATIVE ZOOLOGY
AND
ANATOMY
OF THE
MUSEUM OF
COMPARATIVE ZOOLOGY
AND
ANATOMY

RECEIVED
JAN 10 1900

1-31-90
Vol. 55 No. 21
Pages 3197-3384

Wednesday
January 31, 1990

Best of Federal Register

Briefing on How To Use the Federal Register
For information on a briefing in Washington, DC, see
announcement on the inside cover of this issue.



FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** will be furnished by mail to subscribers for \$340 per year in paper form; \$195 per year in microfiche form; or \$37,500 per year for the magnetic tape. Six-month subscriptions are also available at one-half the annual rate. The charge for individual copies in paper or microfiche form is \$1.50 for each issue, or \$1.50 for each group of pages as actually bound, or \$175.00 per magnetic tape. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or charge to your GPO Deposit Account or VISA or Mastercard.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 55 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-783-3238
Magnetic tapes	275-3328
Problems with public subscriptions	275-3054

Single copies/back copies:

Paper or fiche	783-3238
Magnetic tapes	275-3328
Problems with public single copies	275-3050

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	523-5240
Magnetic tapes	275-3328
Problems with Federal agency subscriptions	523-5240

For other telephone numbers, see the Reader Aids section at the end of this issue.

THE FEDERAL REGISTER

WHAT IT IS AND HOW TO USE IT

- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** The Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

- WHEN:** February 23, at 9:00 a.m.
- WHERE:** Office of the Federal Register,
First Floor Conference Room,
1100 L Street NW., Washington, DC.
- RESERVATIONS:** 202-523-5240.

Contents

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

ACTION

NOTICES

Grants and cooperative agreements; availability, etc.:
MiniGrant Program, 3243

Agency for International Development

NOTICES

Agency information collection activities under OMB review,
3245

Agricultural Marketing Service

RULES

Milk marketing orders:
New York-New Jersey, 3198

Agriculture Department

See Agricultural Marketing Service; Animal and Plant
Health Inspection Service

Air Force Department

NOTICES

Meetings:
Community College Board of Visitors, 3248

Animal and Plant Health Inspection Service

RULES

Interstate transportation of animals and animal products
(quarantine):
Brucellosis in cattle and bison—
State and area classifications, 3200
Overtime services relating to imports and exports:
Work at laboratories, border ports, sea ports, and
airports; fee increase, 3197

Coast Guard

PROPOSED RULES

Regattas and marine parades:
Blue Angels airshow, 3235

Commerce Department

See Export Administration Bureau; International Trade
Administration; National Oceanic and Atmospheric
Administration

Commodity Futures Trading Commission

RULES

Registration:
Feedlot operators; guidelines, 3205

Conservation and Renewable Energy Office

NOTICES

Consumer product test procedures; waiver petitions:
Rheem Manufacturing Co., 3253

Defense Department

See also Air Force Department

RULES

Personnel:
Security clearance; citizenship and residency
requirements for naturalized U.S. citizens, 3223

PROPOSED RULES

Civilian health and medical program of uniformed services
(CHAMPUS):

Physician assistant services; coverage, 3234

NOTICES

Agency information collection activities under OMB review,
3247

Education Department

NOTICES

Agency information collection activities under OMB review,
3248

Grants and cooperative agreements; availability, etc.:

Centers for international business education program,
3338

Schools and teaching improvement reform fund—

Family-school partnership program, 3248

Schools and teachers program; school-level projects,
3249

Employment and Training Administration

NOTICES

Adjustment assistance:

American Shim Steel Co., 3285

A.O. Smith Automotive Products Co. et al., 3288

DeBourgh Manufacturing Co. et al., 3286

Energy Department

See also Conservation and Renewable Energy Office;
Federal Energy Regulatory Commission

NOTICES

Natural gas exportation and importation:

Falcon Seaboard Gas Co., 3255

Unicorp Energy, Inc., 3257

Environmental Protection Agency

PROPOSED RULES

Air pollution; standards of performance for new stationary
sources:

Municipal waste combustors; emission guidelines;
materials separation workshop, 3237

NOTICES

Agency information collection activities under OMB review,
3258

Hazardous waste:

Confidential business information and data transfer to
contractors, 3258

Meetings:

Relative Risk Reduction Strategies Committee, 3259

Science Advisory Board, 3259

Export Administration Bureau

RULES

Export licensing:

Commodity control list—

Truck-manufacturing exports to Kama River and ZIL
truck plants in Soviet Union, 3204

Federal Communications Commission

PROPOSED RULES

Radio and television broadcasting:

Broadcast licensees; distress sale policy; withdrawn, 3239

- Broadcast multiple ownership rules; withdrawn, 3237
- Educational FM and television broadcast station licenses, non-commercial eligibility; withdrawn, 3238
- Public letters; retention requirements eliminated; withdrawn, 3238
- Single majority stockholder and minority incentive provisions reexamination; withdrawn, 3238
- Radio broadcasting:
 - AM broadcast stations; automation of use of measurement data; withdrawn, 3239
 - Metropolitan areas, granting comparative preference; withdrawn, 3240
- Radio services, special:
 - Private operational-fixed microwave service—Video entertainment material; 18 GHz band use, 3241
- Television broadcasting:
 - Television channel allotments; withdrawn, 3240
- NOTICES**
 - Agency information collection activities under OMB review, 3260
 - (4 documents)
 - Committees; establishment, renewal, termination, etc.:
 - World Administrative Radio Conference Advisory Committee, 3261
 - Applications, hearings, determinations, etc.:*
 - Kelly Broadcasting Corp. et al., 3261

Federal Deposit Insurance Corporation

NOTICES

- Meetings; Sunshine Act, 3298

Federal Energy Regulatory Commission

NOTICES

- Electric rate, small power production, and interlocking directorate filings, etc.:
 - Oklahoma Gas & Electric Co. et al., 3250
- Applications, hearings, determinations, etc.:*
 - Carnegie Natural Gas Co., 3251
 - Commonwealth Atlantic Limited Partnership, 3252
 - El Paso Natural Gas Co., 3252
 - Great Lakes Gas Transmission Co., 3252
 - Nycotex Gas Transport, 3253
 - Sea Robin Pipeline Co., 3253

Federal Highway Administration

NOTICES

- Environmental statements; notice of intent:
 - Kenosha County, WI, 3297

Federal Maritime Commission

NOTICES

- Agreements filed, etc., 3262
 - (3 documents)
- Casualty and nonperformance certificates:
 - Epirotiki Lines, Inc., et al., 3263
 - (2 documents)

Federal Mine Safety and Health Review Commission

NOTICES

- Meetings; Sunshine Act, 3298

Federal Reserve System

NOTICES

- Applications, hearings, determinations, etc.:*
 - Daiwa Bank, Ltd., et al., 3263
 - Eagle Bancorp, Inc., 3263
 - Security Bank Holding Co. Employee Stock Ownership Plan, 3264

Federal Trade Commission

NOTICES

- Prohibited trade practices:
 - Reading Hospital et al., 3264

Fish and Wildlife Service

NOTICES

- Endangered and threatened species permit applications, 3279

Food and Drug Administration

RULES

- Animal drugs, feeds, and related products:
 - Lincomycin hydrochloride soluble powder, 3208

PROPOSED RULES

- Human drugs:
 - External analgesic products (OTC)—
 - Fever blister and cold sore treatment products, 3370
 - Skin protectant products (OTC)—
 - Fever blister and cold sore treatment products, 3362

NOTICES

- Food additive petitions:
 - National Starch & Chemical Corp., 3269
- Food for human consumption:
 - Juice and diluted juice beverages; identity standards, 3266
- Medical devices; premarket approval:
 - CIBA 2000 Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses, 3269
 - Storz Ophthalmics, Inc., Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses Models 120UV, S120UV, etc., 3270

Health and Human Services Department

- See* Food and Drug Administration; Health Care Financing Administration; Health Resources and Services Administration; National Institutes of Health; Public Health Service

Health Care Financing Administration

NOTICES

- Medicaid:
 - State plan amendments, reconsideration; hearings—Mississippi, 3271

Health Resources and Services Administration

- See also* Public Health Service

NOTICES

- Meetings; advisory committees:
 - March, 3272

Housing and Urban Development Department

RULES

- Fair housing:
 - Complaint processing; delay notification requirements, 3209
- Low income housing:
 - Elderly or handicapped housing—
 - Projects for nonelderly handicapped families and individuals; correction, 3211

NOTICES

- Agency information collection activities under OMB review, 3274, 3275
 - (2 documents)
- Organization, functions, and authority delegations:
 - Puerto Rico and Virgin Islands; jurisdictional responsibility change from Region II to Region IV, 3273

Interior Department

See Fish and Wildlife Service; Land Management Bureau;
Minerals Management Service; Reclamation Bureau;
Surface Mining Reclamation and Enforcement Office

Internal Revenue Service**RULES****Income taxes:**

Net capital and foreign currency losses attributable to periods after October 31 of taxable years of regulated investment companies, 3211

PROPOSED RULES**Income taxes:**

Net capital and foreign currency losses attributable to periods after October 31 of taxable years of regulated investment companies; cross reference, 3231

International Boundary and Water Commission, United States and Mexico**NOTICES**

Environmental statements; availability, etc.:

Bridge of the Americas (Cordova Bridge), El Paso, TX; lane dividers placement on bridge, 3280

International Development Cooperation Agency

See Agency for International Development

International Trade Administration**NOTICES**

Short supply determinations:

Coater blade steel, 3245

International Trade Commission**NOTICES**

Import investigations:

Carbonated candy products, methods of making, 3281

Crystalline cefadroxil monohydrate, 3282

Environment and wildlife protection; international agreements, 3283

Imported breast prostheses and manufacturing process, 3283

Wire electrical discharge machining apparatus and components, 3284

Interstate Commerce Commission**NOTICES**

Railroad carriers:

Directed service orders—

Atchison, Topeka & Santa Fe Railway Co., 3285

Justice Department

See Parole Commission

Labor Department

See Employment and Training Administration; Occupational Safety and Health Administration

Land Management Bureau**NOTICES**

Mineral interest applications:

Arizona, 3278

Marine Mammal Commission**NOTICES**

Marine Mammal Protection Act:

Marine mammals; taking incidental to commercial fishing operations after October 1, 1993; guidelines availability, 3289

Mexico and United States, International Boundary and Water Commission

See International Boundary and Water Commission, United States and Mexico

Mine Safety and Health Federal Review Commission

See Federal Mine Safety and Health Review Commission

Minerals Management Service**PROPOSED RULES**

Royalty management:

Indian leases; recoupment of overpayments, 3232

NOTICES

Agency information collection activities under OMB review 3280

National Highway Traffic Safety Administration**PROPOSED RULES**

Motor vehicle safety standards:

Lamps, reflective devices, and associated equipment—

Optional combinations of lamps, 3242

NOTICES

Motor vehicle safety standards; exemption petitions, etc.:

Bridgestone (U.S.A.) Inc., 3297

National Institutes of Health**NOTICES**

Committees; establishment, renewal, termination, etc.:

Training Grant and Career Development Review

Committee, 3272

National Oceanic and Atmospheric Administration**RULES**

Fishery conservation and management:

Foreign fishing—

Bering Sea and Aleutian Islands groundfish, 3229

Gulf of Alaska groundfish, 3223, 3230

(2 documents)

NOTICES

Meetings:

Caribbean Fishery Management Council, 3246

Gulf of Mexico Fishery Management Council, 3246

Pacific Fishery Management Council, 3246, 3247

(2 documents)

South Atlantic Fishery Management Council, 3247

Permits:

Endangered and threatened species, 3247

National Science Foundation**NOTICES**

Meetings; Sunshine Act, 3298

Occupational Safety and Health Administration**RULES**

Safety and health standards:

Hazardous chemicals in laboratories; occupational exposure, 3300

Parole Commission**NOTICES**

Meetings; Sunshine Act, 3298

(2 documents)

Postal Rate Commission**PROPOSED RULES**

Practice and procedure rules:

Contract rates; rulemaking petition, 3236

Public Health Service

See also Food and Drug Administration; Health Resources and Services Administration; National Institutes of Health

NOTICES

Organization, functions, and authority delegations:
Alcohol, Drug Abuse, and Mental Health Administration, 3273

Reclamation Bureau**NOTICES**

Environmental statements; availability, etc.:
Los Vaqueros Project, CA, 3279

Securities and Exchange Commission**NOTICES**

Applications, hearings, determinations, etc.:
Arizona Tax Free Fund, Inc., 3290
Canada Life Insurance Co. of New York et al., 3291
Fidelity Investments Life Insurance Co. et al., 3292
General Services Life Insurance Co. et al., 3293
George A. Hormel & Co., 3294
Nationwide Life Insurance Co. et al., 3294

Small Business Administration**RULES**

Small business size standards:
Organizations for handicapped for small business set-asides; eligibility, 3201

NOTICES

Agency information collection activities under OMB review, 3295

Disaster loan areas:

Florida, 3295

Texas, 3296

Washington, 3296

Applications, hearings, determinations, etc.:
Yuzary Capital Funding, Ltd., 3296

Surface Mining Reclamation and Enforcement Office**RULES**

Permanent program and abandoned mine land reclamation plan submissions:
Ohio, 3219

PROPOSED RULES

Permanent program and abandoned mine land reclamation plan submissions:
Indiana, 3233

Transportation Department

See Coast Guard; Federal Highway Administration;
National Highway Traffic Safety Administration

Treasury Department

See Internal Revenue Service

Part IV

Department of Health and Human Services, Food and Drug Administration, 3362

Reader Aids

Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Separate Parts in This Issue**Part II**

Department of Labor, Occupational Safety and Health Administration, 3300

Part III

Department of Education, 3338

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR		672 (2 documents).....	3223, 3230 3229
354.....	3197		
1002.....	3198	675.....	
9 CFR			
78.....	3200		
97.....	3197		
13 CFR			
121.....	3201		
15 CFR			
779.....	3204		
785.....	3204		
799.....	3204		
17 CFR			
3.....	3205		
4.....	3205		
21 CFR			
520.....	3208		
556.....	3208		
Proposed Rules:			
347.....	3362		
348.....	3362		
24 CFR			
103.....	3209		
812.....	3211		
813.....	3211		
885.....	3211		
912.....	3211		
913.....	3211		
26 CFR			
1.....	3211		
602.....	3211		
Proposed Rules:			
1.....	3231		
602.....	3231		
29 CFR			
1910.....	3300		
30 CFR			
935.....	3219		
Proposed Rules:			
218.....	3232		
914.....	3233		
32 CFR			
154.....	3223		
Proposed Rules:			
199.....	3234		
33 CFR			
Proposed Rules:			
100.....	3235		
39 CFR			
Proposed Rules:			
3001.....	3236		
40 CFR			
Proposed Rules:			
51.....	3237		
52.....	3237		
60.....	3237		
47 CFR			
Proposed Rules:			
73 (8 documents).....	3237- 3240 3241		
94.....	3241		
49 CFR			
Proposed Rules:			
571.....	3242		
50 CFR			
611 (2 documents).....	3223, 3229		

Rules and Regulations

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 354

9 CFR Part 97

[Docket No. 90-005]

Fee Increase for Overtime Services

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations that establish charges for Sunday, holiday, or overtime work performed by inspectors of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture at laboratories, border ports, sea ports, and airports. The regulations are amended to: (1) Increase the hourly rates charged a person, firm or corporation having ownership, custody, or control of plants, plant products, animals, animal byproducts, or other commodities or articles subject to certain inspection, laboratory testing, certification, or quarantine and who requires the services of an APHIS employee on a Sunday or holiday or at any other time outside the employee's regular tour of duty; and (2) increase the hourly rates charged an owner or operator of an aircraft requesting inspection or quarantine services at an airport outside of the regularly established hours of service. This action is necessary in order to reflect salary increases for Federal employees in accordance with the Federal Pay Comparability Act of 1970 (Pub. L. 91-656), and subsequent appropriation legislation, and to reflect allowable costs associated with the

implementation of the Debt Collection Act of 1982.

EFFECTIVE DATE: February 11, 1990.

FOR FURTHER INFORMATION CONTACT:

Paul R. Eggert, Director, Resource Management Support, PPQ, APHIS, USDA, Room 621, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7764; or Louise Rakestraw Lothery, Director, Resource Management Support Staff, VS, APHIS, USDA, Room 740, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, (301) 436-7517.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR chapter I, subchapter D, and 7 CFR, chapter III (referred to below as "the regulations"), require inspection, laboratory testing, certification, or quarantine of certain animals, animal byproducts, plants, plant products, or other commodities or articles intended for importation into, or exportation from, the United States. When these services must be provided by an Animal and Plant Health Inspection Service (APHIS) employee on a Sunday or holiday, or at any other time outside the APHIS employee's regular duty hours, the Government charges a fee for the services in accordance with 9 CFR part 97 and 7 CFR part 354.

Each year the fees for these services provided by APHIS employees are reviewed and a cost analysis is performed to determine if such fees are adequate to recover the cost of providing these services. The fees to be charged for these services have been determined by an analysis of data on the current cost of these services; anticipated costs associated with changes in operations of the program; and increases in those costs due to an increase in salaries of Federal employees allocated by Congress under the Federal Pay Comparability Act of 1970 and other increases affecting Federal employees, such as costs for travel and benefits.

In a document published in the Federal Register on December 28, 1989 (54 FR 53325-53326, Docket Number 89-201), we proposed to (1) increase the hourly rates charged for the inspection, laboratory testing, certification, or quarantine services of an APHIS employee on a Sunday or holiday or at

any other time outside the employee's regular tour of duty and (2) increase the hourly rates charged owners or operators of aircraft requesting inspection or quarantine services at an airport outside of the regularly established hours of service.

Comments on the proposed rule were required to be received on or before January 12, 1990. We did not receive any comments. Based on the rationale set forth in the proposal and in this document, we are adopting the provisions of the proposal as a final rule without change.

As a result of this action, with certain exceptions explained below, the rates are increased by \$2.24 per hour for services performed outside the regular tour of duty on a Sunday and by \$1.92 per hour for services performed outside the regular tour of duty on a holiday or any other period. The new rates are \$40.16 and \$31.20, respectively.

The hourly rates charged an owner or operator of an aircraft requesting inspection or quarantine services at an airport outside of the regularly established hours of service are increased as follows: For services performed outside of the regularly established hours of service on a Sunday, the rate is increased by \$1.44 per hour, to \$32.60. For services performed outside of the regularly established hours of service on a holiday or any other period, the rate is increased by \$1.20 per hour, to \$24.88.

Owners and operators of aircraft will continue to be provided inspection services without reimbursement during regularly established hours of service on a Sunday or holiday. Further, there is no change in the \$25.00 limit for all private aircraft or private vessel inspection services performed on a Sunday, holiday, or at any time after 5 p.m. or before 8 a.m. on a weekday by the Customs Service, Immigration and Naturalization Service, Public Health Service, and the Department of Agriculture.

Effective Date

Pursuant to the administrative procedure provisions in 5 U.S.C. 553, we find good cause for making this rule effective less than 30 days after publication in the Federal Register. This is a full cost recovery program. In order

to allow for orderly implementation and maximum recovery of costs, the rule will be effective the beginning of the first pay period following signature.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Based on information compiled by the Department, we estimate that for calendar year 1989 APHIS provided an average of 12,780 hours per week of services for which charges were assessed. These services were requested by thousands of entities. We do not expect that the number of hours of service for which charges will be imposed will increase significantly in 1990.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects

7 CFR Part 354

Agricultural commodities, Exports, Government employees, Imports, Plants (Agriculture), Quarantine, Transportation.

9 CFR Part 97

Exports, Government employees, Imports, Livestock and livestock products, Poultry and poultry products, Transportation.

Accordingly, 7 CFR part 354 and 9 CFR part 97 are amended as follows:

Title 7—[AMENDED]

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

1. The authority citation for 7 CFR part 354 continues to read as follows:

Authority: 7 U.S.C. 2260; 49 U.S.C. 1741; 7 CFR 2.17, 2.51 and 371.2(c).

§ 354.1 [Amended]

2. In paragraph (a)(1) introductory text of § 354.1, "\$37.92" is removed and "\$40.16" is added in its place, and "\$29.28" is removed and "\$31.20" is added in its place.

§ 354.1 [Amended]

3. In paragraph (a)(1)(iii) of § 354.1, "\$31.16" is removed and "\$32.60" is added in its place, and "\$23.68" is removed and "\$24.88" is added in its place.

Title 9—[AMENDED]

PART 97—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

4. The authority citation for 9 CFR part 97 continues to read as follows:

Authority: 7 U.S.C. 2260; 49 U.S.C. 1741; 7 CFR 2.17, 2.51 and 371.2(d).

§ 97.1 [Amended]

5. In paragraph (a) introductory text of § 97.1, "\$37.92" is removed and "\$40.16" is added in its place, and "\$29.28" is removed and "\$31.20" is added in its place.

§ 97.1 [Amended]

6. In paragraph (a)(3) of § 97.1, "\$31.16" is removed and "\$32.60" is added in its place, and "\$23.68" is removed and "\$24.88" is added in its place.

Done in Washington, DC., this 25th day of January 1990.

Larry B. Slagle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-2181 Filed 1-30-90; 8:45 am]

BILLING CODE 3410-34-M

Agricultural Marketing Service

7 CFR Part 1002

[Docket No. AO-71-A77; DA-88-105]

Milk in the New York-New Jersey Marketing Area; Order Amending Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action changes the New York-New Jersey Federal milk order with respect to the dates by which payments are to be made to producers, to cooperatives, and to and from the producer-settlement fund, and by which the market administrator is to announce the uniform prices to producers. Most of the dates are 5 days earlier than specified in the current order provisions. The changes will allow for earlier payments to producers and will accommodate economic changes resulting from recent New York State legislation that requires that producers receive their final payment for milk each month on or before the 20th day of the following month.

The changes are based on a public hearing held June 27-July 21, 1988, and November 14-16, 1988. Other issues considered at the hearing included proposed amendments to the New England and Middle Atlantic Federal milk orders, as well as other proposed changes to the New York-New Jersey order. Only those changes dealing with the timing and number of payments to producers, and related reporting and announcement requirements are included in this final order. These changes are necessary to reflect current marketing conditions and maintain orderly marketing in the New York-New Jersey marketing area.

More than two-thirds of the producers who voted in a referendum approved the issuance of the amended order.

EFFECTIVE DATE: January 29, 1990.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, room 2968, South Building, P.O. Box 96456, Washington, DC 20090-6456, (202) 447-7183.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing: Issued June 7, 1988; published June 10, 1988 (53 FR 21825). Supplemental Notice of Hearing: Issued September 29, 1988; published October 4, 1988 (53 FR 38963).

Notice of Re-opened Hearing: Issued August 10, 1989; published August 16, 1989 (54 FR 33709).

Partial Recommended Decision: Issued September 20, 1989; published September 26, 1989 (54 FR 39377).

Recommended Decision: Issued October 31, 1989; published November 8, 1989 (54 FR 46904).

Tentative Decision: Issued November 8, 1989; published November 15, 1989 (54 FR 47527).

Interim Final Order: Issued November 28, 1989; published December 4, 1989 (54 FR 49955).

Partial Final Decision: Issued December 12, 1989; published December 18, 1989 (54 FR 51749).

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the New York-New Jersey order was first issued and when it was amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and the applicable rules of practice and procedure governing the formation of marketing agreements and marketing orders (7 CFR part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the New York-New Jersey marketing area.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing area; and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as hereby amended regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary in the public interest to make this order amending the order effective not later than January 29, 1990. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing area.

The provisions of this order are known to handlers. The partial recommended decision of the Administrator was issued September 20, 1989 (54 FR 39377), and the partial final decision of the Assistant Secretary containing all amendment provisions of this order was issued December 12, 1989 (54 FR 51749). The changes effected by this order will not require extensive preparation or substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order effective January 29, 1990, and that it would be contrary to the public interest to delay the effective date of this order for 30 days after its publication in the Federal Register. (Sec. 553(d), Administrative Procedure Act, 5 U.S.C. 551-559.)

(c) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in sec. 8c(9) of the Act) of more than 50 percent of the milk, which is marketed within the marketing area, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of this order amending the order is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the order; and

(3) The issuance of the order amending the order is approved or favored by at least two-thirds of the producers who participated in a referendum and who during the determined representative period were engaged in the production of milk for sale in the marketing area.

List of Subjects in 7 CFR Part 1002

Dairy products, Milk, Milk marketing orders.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, the handling of milk in the New York-New Jersey marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, as follows:

PART 1002—MILK IN THE NEW YORK-NEW JERSEY MARKETING AREA

1. The authority citation for 7 CFR part 1002 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

§ 1002.22 [Amended]

2. In § 1002.22 Additional duties of the market administrator, paragraph (m)(2) is amended by changing "15th" to "14th".

3. In § 1002.30 Reports of receipts and utilization, the introductory text is revised to read as follows:

§ 1002.30 Reports of receipts and utilization.

Each handler, except a handler receiving own farm milk and not required to be listed pursuant either to § 1002.11 or § 1002.12, shall report each month to the market administrator for the preceding month in the manner and on the forms prescribed by the market administrator with respect to each pool plant, partial pool plant, pool unit or partial pool unit operated by such person, the information set forth in paragraphs (a) through (d) of this section. Such report shall be physically received at the office of the market administrator no later than the close of business on the 10th day of the month. Other information required to be reported no later than the 10th day of the month pursuant to §§ 1002.25 and 1002.31 must also be physically received by the market administrator no later than the 10th day of the month.

* * * * *

4. In § 1002.50a Class prices, the introductory text is revised to read as follows:

§ 1002.50a Class prices.

For pool milk received during each month from dairy farmers or cooperative associations of producers, each handler shall pay per hundredweight not less than the prices set forth in this section, subject to the differentials and adjustments §§ 1002.51 and 1002.81. Any handler who purchases or receives milk during any month from a cooperative association of producers but does not operate the plant or unit receiving this milk from producers shall pay the cooperative association on or before 2 days before the last day of the month if paid by check, or the last day of the month if paid in cash or cash equivalent, at not less than the lowest class price pursuant to this section for the preceding month for milk received from such cooperative during the first 15 days of the month, and shall pay the

cooperative association on or before the 15th day of the following month the balance due for milk received during the month from such cooperative at not less than the class prices pursuant to this section subject to the differentials and adjustments set forth in §§ 1002.51 and 1002.81 applicable at the plant at which the milk is first received from the cooperative association. Such payments to a cooperative association shall be deemed not to have been made until the payments have been received by the cooperative association.

5. In § 1002.80 Time and rate of payments, paragraphs (c) through (f) are redesignated as paragraphs (d) through (g); paragraph (b) is redesignated as paragraph (c) and revised; paragraph (a) is redesignated as paragraph (b) and the introductory text of newly designated paragraph (b) is revised; and a new paragraph (a) is added, as follows:

§ 1002.80 Time and rate of payments.

(a) On or before the last day of the month, each handler shall make payment to each producer for milk received from such producer during the first 15 days of the month at not less than the lowest class price for the preceding month.

(b) On or before the 20th day of the month, each handler shall make payment, pursuant to paragraphs (c), (d), (e), (f) and (g) of this section, to each producer for the balance due for all milk received from such producer during the preceding month at not less than the uniform price for such month, subject to the following adjustments:

(c) Upon receipt of a written request from a cooperative association which the market administrator determines is authorized by its producer-members to collect payment for their milk, each handler, on or before 2 days before payments are due to individual producers if paid by check, or the same day such payments are due to individual producers if paid in cash or cash equivalent, shall pay the cooperative association for milk received during the month from the producer-members of such association an amount equal to not less than the total amount otherwise due such producer-members as determined pursuant to paragraphs (a) and (b) of this section.

§ 1002.85 [Amended]

6. § 1002.85 Payments to the producer-settlement fund, is amended by changing the language "21st" to "16th".

§ 1002.86 [Amended]

7. In § 1002.86 Payments out of the producer-settlement fund, paragraph (a) is amended by changing "22nd" to "17th", and paragraph (b) is amended by changing "25th" to "20th".

§ 1002.89 [Amended]

8. In § 1002.89 Cooperative payments for marketwide services, paragraph (f)(1) is amended by changing "25th" to "20th".

Signed at Washington, DC, on January 25, 1990.

John E. Frydenlund,
Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 90-2180 Filed 1-30-90; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 90-012]

Brucellosis in Cattle; State and Area Classifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: We are amending the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Indiana from Class A to Class Free. We have determined that Indiana now meets the standards for Class Free status. This action relieves certain restrictions on the interstate movement of cattle from Indiana.

DATES: Interim rule effective January 26, 1990. Consideration will be given only to comments received on or before April 2, 1990.

ADDRESSES: To help ensure that your written comments are considered, send an original and three copies of written comments to Regulatory Analysis and Development, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket Number 90-012. Comments received may be inspected at USDA, Room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. G. Frye, Chief Staff Veterinarian, Cattle Diseases and Surveillance Staff, VS, APHIS, USDA, Room 731, Federal

Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-5533.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and man, caused by bacteria of the genus *Brucella*.

The brucellosis regulations contained in 9 CFR part 78 (referred to below as the regulations) provide a system for classifying States or portions of States according to the rate of brucella infection present, and the general effectiveness of a brucellosis control and eradication program. The classifications are Class Free, Class A, Class B, and Class C. States or areas that do not meet the minimum standards for Class C are required to be placed under Federal quarantine.

The brucellosis Class Free classification is based on a finding of no known brucellosis in cattle for the 12 months preceding classification as Class Free. The Class C classification is for States or areas with the highest rate of brucellosis. Class B and Class A fall between these two extremes. Restrictions on moving cattle interstate become less stringent as a State approaches or achieves Class Free status.

The standards for the different classifications of States or areas entail maintaining (1) a cattle herd infection rate not to exceed a stated level during 12 consecutive months; (2) a rate of infection in the cattle population (based on the percentage of brucellosis reactors found in the Market Cattle Identification (MCI) program—a program of testing at stockyards, farms, ranches, and slaughtering establishments) not to exceed a stated level; (3) a surveillance system that includes testing of dairy herds, participation of all slaughtering establishments in the MCI program, identification and monitoring of herds at high risk of infection—including herds adjacent to infected herds and herds from which infected animals have been sold or received, and having an individual herd plan in effect within a stated number of days after the herd owner is notified of the finding of brucellosis in a herd he or she owns; and (4) minimum procedural standards for administering the program.

Before the effective date of this interim rule, Indiana was classified as a Class A State because of its herd infection rate and its MCI reactor prevalence rate. However, after reviewing its brucellosis program records, we have concluded that the

State of Indiana meets the standards for Class Free status.

To attain and maintain Class Free Status, a State or area must (1) remain free from field strain *Brucella abortus* infection for 12 consecutive months or longer, (2) maintain a 12-consecutive-month MCI reactor prevalence rate not to exceed one reactor per 2,000 cattle tested (0.050 percent), and (3) have an approved individual herd plan in effect within 15 days of locating the source herd or recipient herd. Indiana now meets the standards for classification as Class Free.

Therefore, we are removing Indiana from the list of Class A States in § 78.41(b) and adding it to the list of Class Free States in § 78.41(a). This action relieves certain restrictions on moving cattle interstate from Indiana.

Immediate Action

James W. Glosser, Administrator of the Animal and Plant Health Inspection Service, has determined that there is good cause to publish this interim rule without prior opportunity for public comment. Immediate action is warranted to remove unnecessary restrictions on the interstate movement of cattle from Indiana.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this interim rule in the *Federal Register*. After the comment period closes, we will publish another document in the *Federal Register*, including discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-

based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the status of Indiana from Class A to Class Free reduces certain testing and other requirements governing the interstate movement of cattle from Indiana. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Indiana, as well as buyers and importers of Indiana cattle.

There are an estimated 38,000 herds in Indiana, 99 percent of which are owned by small entities, which potentially would be affected by this rule. Most of these herds are not certified-free. Test-eligible cattle offered for sale from other than certified-free herds must have a negative test under present Class A status regulations. Last year Indiana tested 51,462 cattle for change-of-ownership. This testing costs approximately \$7 per head or \$360,234. If change-of-ownership testing is distributed equally among all herds, Class Free status would potentially save less than \$10.00 for each small business.

Therefore, we have determined that changing Indiana's brucellosis status will not significantly affect market patterns, and will not have a significant economic impact on the small entities affected by this interim rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 9 CFR Part 78

Animal diseases, Brucellosis, Cattle, Hogs, Quarantine, Transportation.

Accordingly, we are amending 9 CFR part 78 follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 continues to read as follows:

Authority: 21 U.S.C. 111-114a-1, 114g, 115, 117, 120, 121, 123-126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

§ 78.41 [Amended]

2. Section 78.41, paragraph (a) is amended by adding "Indiana," immediately before "Maine".

§ 78.41 [Amended]

3. Section 78.41, paragraph (b) is amended by removing "Indiana".

Done in Washington, DC, this 26th day of January 1990.

Larry B. Slagle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-2182 Filed 1-30-90; 8:45 am]

BILLING CODE 3410-34-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245

Eligibility of Organizations for the Handicapped for Small Business Set-Asides

AGENCY: Small Business Administration.
ACTION: Interim final rule.

SUMMARY: The Small Business Administration (SBA) is amending its regulations to enlarge the class of organizations eligible for award of Small Business Set-Aside contracts to include public and private organizations for the handicapped, to define the terms under which such organizations may qualify for such awards, and to provide methods to consider protests of eligibility of organizations for the handicapped or appeals of small businesses alleging prospective severe economic injury if a specific award is made to an organization for the handicapped. These amendments implement section 313 of the Small Business Administration Reauthorization and Amendment Act of 1988 (Pub. L. 100-590).

DATES: Comments must be received no later than March 2, 1990.

ADDRESSES: Written comments should be addressed to: Associate Administrator for Procurement Assistance, Small Business

Administration, 1441 L Street NW., Room 600, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT. Gene VanArsdale, Director, Office of Procurement Policy and Liaison, 202/653-6588.

SUPPLEMENTARY INFORMATION: These amendments implement section 133 of the Small Business Administration Reauthorization and Amendment Act of 1988 (Pub. L. 100-590). Section 133 enlarged eligibility for award of Small Business Set-Aside contracts to include public and private organizations for the handicapped. Small business Set-Asides are procurements in which competition is restricted to firms which qualify as small businesses under the definitions established by SBA. In addition to expanding eligibility for these set-asides, the law defines the terms under which the organizations may qualify for such awards; and, also establishes a right of appeal for small businesses which experience, or are likely to experience "severe economic injury" as the result of a proposed award to an organization for the handicapped. The method which has been determined by SBA to be the most suitable means for alleviating economic impact is to assure that the affected small business has the opportunity to win award of the contract in question; and this is also the method for fulfilling the statutory obligation which is least disruptive to the procurement process. It is therefore SBA policy, when severe economic injury is found, to seek award of the contract without regard to offers by organizations for the handicapped.

Section-by-Section Review

Section 121.2001 describes the underlying policy of permitting public and private organizations for the handicapped to participate in Federal procurements which are set-aside for small business. It notes the total dollar limits on such participation. It also describes an appeal right which the SBA Reauthorization Act provides for small businesses which experience or are likely to experience severe economic injury as a result of award of set-asides to such organizations. Such small businesses may appeal the award to SBA. The final agency decision on the appeals will be made by the Associate Administrator for Procurement Assistance as the delegatee of the Administrator. The section also sets forth the remedy for such severe injury: removal of the eligibility of the organizations for the handicapped for award of the contract at issue.

Section 121.2002 provides definitions of "public or private organizations for

the handicapped" and "handicapped individual". Although Public Law 100-590 provided that the definition for public or private organizations for the handicapped would be as set forth in section 3(e) of the Small Business Act the definition contained in this rule omits the portion of the statutory definition found in subparagraph 3(e)(3). This omission is required because subparagraph 3(e)(3) provides limitations on the organizations in terms of financial assistance, which is not involved in contract awards. Additionally, the portion of subparagraph 3(e)(3) which requires that 75 per cent of the labor be performed by handicapped individuals, is separately addressed in Public Law 100-590, and separately implemented in this proposed rule by § 121.2003.

In § 121.2003 the eligibility of sheltered workshops for Small Business Set-Asides is established, including the requirement that at least 75 per cent of the direct labor performed on each item being produced, or on each type of service being performed, must be performed by handicapped individuals. This section also notes that organizations for the handicapped cease to be eligible for such set-asides when the aggregate limits for such awards during a fiscal year have been reached.

The procedure for protesting the eligibility of sheltered workshops is described in § 121.2004. These rules are modeled on long-established rules for protesting the small business status of another offeror on a Federal procurement. The essential differences are that the determinations would be made at the Central Office of the SBA, rather than at a regional office; the Committee for Purchase from the Blind and Other Severely Handicapped would be consulted; and, the determination would be the final administrative remedy at SBA. The section also describes the documentation which will establish the eligibility of an organization for the handicapped.

The provisions of § 121.2005 describe the process for appeal of awards to organizations for the handicapped by small businesses who allege severe economic injury has been or will be suffered as a result of award of a contract to an organization for the handicapped. Reasonable grounds for appeal are described and a presumption is established that 25 per cent or more of a small business' annual receipts is "severe". The level of 25 per cent has been selected because, in the absence of other persuasive data, it conforms to the level selected for SBA's "8(a)" program which also conducts reviews of

economic impact upon competing candidates for contracts. The procedure for appeal is again modeled on the process for protesting small business status but would include a 10-day period for filing appeals, as set forth in the law. The remedy provided is the only reasonable means to assure direct alleviation consistent with the reasonable needs for prompt and efficient Federal procurement processes. Here, also, determinations will be made at the Central Office of the SBA and will be the final administrative remedy.

Compliance With Executive Orders 12291 and 12612, the Administrative Procedure Act (5 U.S.C. 551 et seq.), the Regulatory Flexibility Act (55 U.S.C. 601, 601, et seq.), and the Paperwork Reduction Act (44 U.S.C. chap. 35)

SBA has determined that this rule does not constitute a major rule for purposes of Executive Order 12291 because the national effect on the economy will not exceed \$100 million. The statutory limit on the program does not exceed \$50 million in any one year and SBA's previous experience with a similar program showed less than \$10 million to be involved.

This rule addresses the participation of organizations for the handicapped in small business set-asides. With the exception of the appeal procedures set forth in §§ 121.2003 and 121.2004 this program is currently addressed by the Federal Acquisition Regulations (FAR) at 48 CFR 19.501(k). Since the appeal procedures are necessary to protect certain small businesses from "severe economic injury," this rule is being published without prior notice and comment as permitted by 5 U.S.C. 553(b)(3). However, public comments will be accepted for 30 days from the date of publication in the Federal Register. Subsequent to review and consideration of the public comments, SBA will publish a final rule relating to the participation of organizations for the handicapped in small business set-asides.

SBA certifies that this rule does not warrant the preparation of a Federalism Assessment in accordance with Executive Order 12612.

For purposes of compliance with the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., SBA certifies that this rule will not have a significant effect on a substantial number of small entities while it is possible that 10 or more small entities might use these appeal procedures, such a contingency is not anticipated.

For purposes of the Paperwork Reduction Act, 44 U.S.C. ch. 35, SBA

certifies that this rule will impose no new reporting or recordkeeping requirements.

For the reasons set forth above, title 13, Code of Federal Regulations (CFR) is amended as set forth below.

PART 121—SMALL BUSINESS SIZE REGULATIONS

1. The authority citation for 13 CFR part 121 is revised to read as follows:

Authority: Sections 3(a) and 5(b)(6) of the Small Business Act, as amended (15 U.S.C. 632(a), 634(b)(6), 644(a)), and Pub. L. 100-656, 102 Stat. 3853 (1988).

2. Part 121 is amended by adding subpart B to read as follows:

Subpart B—Other Eligibility Provisions

Eligibility of Organizations for the Handicapped for Small Business Set-Asides

Sec.	
121.2001	Statutory basis.
121.2002	Definitions.
121.2003	Eligibility.
121.2004	Protest of eligibility.
121.2005	Appeal of economic impact.

Subpart B—Other Eligibility Provisions

Eligibility of Organizations for the Handicapped for Small Business Set-asides

§ 121.2001 Statutory basis.

(a) The Small Business Act as amended by public law 100-590 provides that public or private organizations for the handicapped shall be eligible to participate in Federal procurements which are set aside for small business, during fiscal years 1989 through 1993, in aggregate amounts of not more than \$30,000,000 in 1989; \$40,000,000 in 1990; and \$50,000,000 each year in 1991 through 1993.

(b) That law further provides for appeal to SBA of such an award when a small business experiences or is likely to experience severe economic injury as a result of the proposed award to an organization for the handicapped. Any eligible concern wishing to appeal must file its appeal with the Administrator of the SBA within 10 days after the announcement of the proposed award to which the appeal relates. SBA is afforded 30 days from the date the appeal is filed to consult with the Executive Director of the Committee for Purchase from the Blind and Other Severely Handicapped and to resolve the appeal. If SBA finds that severe economic injury has occurred or is likely to occur, the statute further directs SBA to require each agency and department having procurement powers to take such action as may be appropriate to alleviate such severe economic injury,

which action shall, under these regulations, be award of the contract without regard to offers by organizations for the handicapped.

§ 121.2002 Definitions.

(a) "Organization for the handicapped" means a public or private entity:

(1) Which is organized under the laws of the United States or any state, operated in the interest of handicapped individuals, the net income of which does not inure in whole or in part to the benefit of any shareholder or other individual; and,

(2) Which complies with any applicable health and safety.

(b) "Handicapped individual" means a person who has a physical, mental, or emotional impairment, defect, ailment, disease, or disability of a permanent nature which in any way limits the selection of any type of employment for which the person would otherwise be qualified or qualifiable.

§ 121.2003 Eligibility.

Organizations for the handicapped shall be eligible for award of contracts set aside for small business provided that:

(a) The workshop meets the definition in § 121.2002(a);

(b) At least 75 per centum of the direct labor performed on each item being produced by the organization for the handicapped under the contract or performed in providing each type of service under the contract is performed by handicapped individuals; and,

(c) The maximum allowable amount of such awards has not been reached.

§ 121.2004 Protest of eligibility.

(a) *Who may protest.* A responsive offeror, the affected contracting officer, or the Small Business Administration may protest the status of an offeror as an organization for the handicapped eligible for participation in small business set-asides.

(b) *Grounds for protest.* Protests must include specific information which tends to show that the protested organization does not meet the definition set forth in 121.2002 above.

(c) *Procedure for protest.* (1) Protests shall be submitted to the Associate Administrator for Procurement Assistance, Small Business Administration, 1441 L Street, NW., Washington DC 20416, with a copy to the contracting officer for the procurement in question. The Associate Administrator shall be the deciding official for purposes of protests under this section.

(2) Protests, including copies, shall be delivered by hand, telegram or be placed in the U.S. mail prior to the close of business on the fifth working day after bid opening or, in the case of a negotiated procurement, the fifth working day after receipt of notification of the identity of the apparent successful offeror.

(3) The Associate Administrator for Procurement Assistance shall notify the protested organization in writing that a protest concerning its eligibility for small business set-asides has been presented.

(4) The protested organization shall deliver required documentation, with any other documentation or information it wishes SBA to consider within three business days of receipt of written notification of the protest. See paragraphs (d) and (e) of this section. Delivery may be made by hand, telegram or placement in the U.S. mail.

(5) The Associate Administrator for Procurement Assistance shall consult with the Executive Director of the Committee for Purchase from the Blind and Severely Handicapped before rendering a determination.

(6) SBA shall, within ten business days of receipt of a protest, notify parties, including the contracting officer, of its decision. Notification will be considered complete upon hand delivery, receipt of a telegram, or placement in the U.S. mail.

(7) The eligibility determination by the Associate Administrator shall be the final Agency action with respect to such protests.

(8) Failure to submit any documentation required to resolve a protest may be grounds for resolution of the protest against the non-submitting party.

(d) *Required documentation to demonstrate eligibility.* Except as provided in paragraph (e) of this section, the following documentation, where applicable, will be required to demonstrate the eligibility of an organization:

(1) A legible copy (preferably a photocopy) of the articles of incorporation showing the date of filing and the signature of an appropriate State official.

(2) A copy of the bylaws certified by an officer of the corporation.

(3) If the articles of incorporation or bylaws do not include a statement to the effect that no part of the net income of the workshop may inure to the benefit of any shareholder or other individual, one of the following documents:

(i) A certified copy of the State statute under which the workshop was

incorporated which includes wording to the effect that no part of the net income of the workshop may inure to the benefit of any shareholder or other individual.

(ii) A copy of a resolution approved by the governing body of the corporation, certified by an officer of the corporation to the effect that no part of the net income of the workshop may inure to the benefit of any shareholder or other individual.

(iii) A copy of the Internal Revenue Service certificate, duly executed during the prior twelve months, indicating that the corporation has been accepted as a non-profit agency for taxation purposes.

(e) A State-owned or State-operated workshop for the blind or other severely handicapped shall demonstrate its eligibility by submitting the following documents:

(1) A certified copy of the State statute establishing or authorizing the establishment of workshop(s) for the handicapped.

(2) In the case of a wholly-owned State corporation, a certified copy of the corporation bylaws; and, in the case of a State agency, a certified true copy of implementing regulations, operating procedures, notice of establishment of the workshop, or other similar documents.

§ 121.2005 Appeal of economic impact.

(a) *Who may appeal.* Any for-profit small business concern that has experienced or is likely to experience severe economic injury as the result of a proposed award of a small business set-aside to an organization for the handicapped may appeal to SBA.

(b) *Grounds for appeal.* Severe economic injury will be shown by evidence that, absent competition by organizations for the handicapped, the appellant is likely to receive the award, and:

(1) The subject contract would represent a significant portion of the appellant's sales; or,

(2) The appellant has participated as an offeror in other procurement solicitations which were awarded to organizations for the handicapped and which cumulatively represent a significant portion of the protestor's sales; or,

(3) The appellant has been a continuous supplier of the product or service to the Government and is significantly dependent upon that market; or,

(4) The appellant is the prior incumbent contractor on a continuing or recurring requirement and the contract is significant in the context of the protestor's business.

(5) Levels of 25 per cent or more are presumed to be significant.

(c) *Procedure for appeal.* (1) Appeals shall be submitted to the Associate Administrator for Procurement Assistance, Small Business Administration, 1441 L Street NW., Washington DC 20416 with a copy to the contracting officer. The Associate Administrator shall be the deciding official for purposes of appeals under this section.

(2) Appeals including copies, shall be delivered by hand, telegraph, or placed in the U.S. mail, by the close of business of the tenth calendar day after opening of bids, or, in the case of negotiated procurements, after receipt of notification of the identity of the apparent successful offeror.

(3) The Associate Administrator shall consult with the Executive Director of the Committee for Purchase from the Blind and Other Severely Handicapped and shall resolve the appeal within ten working days after its receipt.

(4) The Associate Administrator shall, within ten working days of receipt of an appeal, notify appellants and affected contracting officers of SBA's decision and require the contracting officer to proceed with award or to make an award without regard to offers by organizations for the handicapped. Notice shall be complete upon hand delivery, delivery by telegram or placement in the U.S. mail.

(5) The decision by the Associate Administrator shall be the final agency action with respect to such appeals.

Dated: December 13, 1989.

Susan S. Engeleiter,
Administrator.

[FR Doc. 90-1339 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 779, 785 and 799

[Docket No. 900113-0013]

Removal of Foreign Policy Controls on Exports to Kama River and ZIL Truck Plants in the Soviet Union

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: Section 6 of the Export Administration Act of 1979, as amended, authorizes the imposition of export controls to further the foreign policy of the United States or to fulfill its declared international obligations. Under the Act,

foreign policy controls expire annually unless extended. The Secretary of Commerce, following consultation with the Department of State, sent a report to Congress on January 19, 1990 extending all existing foreign policy controls except controls on technical data and equipment for the manufacture of trucks at the Soviet Kama River (Kam AZ) and ZIL truck plants.

This rule removes the foreign policy controls placed on truck-manufacturing exports whose destination is the Kama River or ZIL truck plants in the Soviet Union by amending 15 CFR parts 779, 785 and 799. In addition, in Commodity Group 3 (General Industrial Equipment) of the Commodity Control List (Supplement No. 1 to § 799.1), ECCN 6398G is removed.

EFFECTIVE DATE: This rule is effective January 21, 1990.

FOR FURTHER INFORMATION CONTACT: Kathryn Sullivan, Regulations Branch, Office of Technology and Policy Analysis, Bureau of Export Administration, Telephone: (202) 377-4479.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves collections of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694-0005 and 0694-0023. There will be an insignificant decrease in the burden hours associated with the OMB No. 0694-0023 collection as a result of this rule, and an insignificant decrease in applications for an export license (OMB No. 0694-0005).

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. Section 13(a) of the Export Administration Act of 1979 (EAA), as amended (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative

Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Accordingly, it is being issued in final form. However, comments from the public are always welcome. Comments should be submitted to Kathryn Sullivan, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Parts 779, 785 and 799

Communist countries, Exports, Reporting and recordkeeping requirements.

Accordingly, parts 779, 785 and 799 of the Export Administration Regulations (15 CFR parts 768-799) are amended as follows:

1. The authority citation for 15 CFR parts 779, 785 and 799 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 [50 U.S.C. app. 2401 *et seq.*], as amended by Pub. L. 97-145 of December 29, 1981, by Pub. L. 100-418 of August 23, 1988; and by Pub. L. 99-64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95-223 of December 28, 1977 (50 U.S.C. 1701 *et seq.*); E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99-440 of October 2, 1986 (22 U.S.C. 5001 *et seq.*); and E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986).

PART 779—[AMENDED]

2. Section 779.4(f) is amended by revising paragraph (f)(1) introductory text as set forth below and by removing paragraph (f)(1)(i)(R).

§ 779.4 General license GTDR: technical data under restriction.

(f) * * *

(1) *Requirement of written assurance for certain data, services, and materials.* No export of technical data of the kind described in paragraph (f)(1)(i) of this section may be made under the provisions of this General License GTDR until the exporter has received written assurance from the importer that neither the technical data nor the direct

product¹⁹ thereof is intended to be shipped, either directly or indirectly, to Country Group Q, S, W, Y, or Z, or Afghanistan or the People's Republic of China, except as provided in paragraph (f)(1)(ii) of this section. The required assurance may be in the form of a letter or other written communication from the importer evidencing such intention, or a licensing agreement that restricts disclosure of the technical data to use only in a country other than Country Group Q, S, W, Y, or Z, or Afghanistan or the People's Republic of China and prohibits shipments of the direct product¹⁹ thereof by the licensee to Country Group Q, S, W, Y, or Z, or Afghanistan or People's Republic of China. An assurance included in a licensing agreement will be acceptable for all exports made during the life of the agreement. If such assurance is not received, this general license is not applicable and a validated export license is required. An application for such validated license shall include an explanatory statement setting forth the reasons why such assurance cannot be obtained. In addition, this general license is not applicable to any export of technical data of the kind described in paragraph (f)(1)(i) of this section if, at the time of export of the technical data from the United States, the exporter knows or has reason to believe that the direct product to be manufactured abroad by use of the technical data is intended to be exported or reexported, directly or indirectly, to Country Group Q, S, W, Y, or Z, or Afghanistan or the People's Republic of China.

¹⁹ The term "direct product," as used in this sentence and in this context only, is defined to mean the immediate product (including processes and services) produced directly by use of the technical data, except that petroleum or chemical products other than molecular sieves or catalysts are not included in this definition. The coverage of the term does not extend to the results of the use of such "direct product." An example of the direct product of technical data is reforming process equipment designed and constructed by use of the technical data exported, but the aromatics produced by the reforming process equipment are not immediate or direct products of these technical data. However, if the technical data are a formula for producing aromatics, the aromatics, although they are immediate products of the data, are not included in this definition of direct product, since they are petroleum products. Conversely, if the technical data are a formula for producing either molecular sieves or catalysts, the foreign-produced molecular sieves and catalysts are including in the definition of direct product.

²⁰ Effective April 26, 1971, Country Group W no longer included Romania. Assurances executed prior to April 26, 1971 and referring to Country Group W continue to apply to Romania as well as Poland. Effective June 2, 1980, Hungary was added to Country Group W, which at that time included only Poland. Assurances executed prior to June 2, 1980 and referring to Country Group Y continue to apply to Hungary. Assurances executed on or after June 2, 1980 and referring to Country Group W apply to Hungary as well as Poland.

PART 785—[AMENDED]

§ 785.2 [Amended]

3. Section 385.2 is amended by removing paragraph (e).

PART 799—[AMENDED]

§ 799.1 [Amended]

4. Section 799.1 is amended by revising in paragraph (f)(4)(iii) the phrase "(e.g., South African military and police, Soviet Kama River and ZIL truck plants)" to read "(e.g., South African military and police)".

Supplement No. 1 [Amended]

5. In Supplement No. 1 to § 799.1 (the Commodity Control List), in Commodity Group 3 (General Industrial Equipment), Export Control Commodity Number 6398C is removed.

Dated: January 24, 1990.

James M. LeMunyon,
Deputy Assistant Secretary for Export
Administration.

[FR Doc. 90-2024 Filed 1-30-90; 8:45 am]

BILLING CODE 2510-DT-M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 3 and 4

Registration Guidelines for Feedlot Operators

AGENCY: Commodity Futures Trading Commission.

ACTION: Statement of agency interpretation.

SUMMARY: The Commodity Futures Trading Commission ("Commission" or "CFTC") is issuing the following guidelines concerning registration requirements for feedlot operators. These guidelines supersede comments previously provided by the Commission's Division of Trading and Markets on this subject in Advisory 88-1 "Registration Requirements for Feedlot Operators," 2 Comm. Fut. L. Rep. [CCH] ¶24,218 (April 6, 1988) ["Advisory 88-1"].

EFFECTIVE DATE: January 31, 1990.

ADDRESSES: Interested persons may submit comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Reference should be made to Registration Guidelines for Feedlot Operators.

FOR FURTHER INFORMATION CONTACT: Lawrence B. Patent, Esq., Associate Chief Counsel, Division of Trading and Markets, 2033 K Street NW.,

Washington, DC 20581, telephone: (202) 254-8955.

SUPPLEMENTARY INFORMATION: On April 6, 1988, the Commission's Division of Trading and Markets ("Division") issued Advisory 88-1, which addressed various registration issues in the context of six factual scenarios concerning a hypothetical feedlot operator offering its feedlot customers certain futures-related hedging services in conjunction with its cash market operations. The Commission has received requests to modify Advisory 88-1 to permit feedlot operators to provide limited commodity trading advice—without compensation¹ in the context of hedging services ancillary to feedlot services—without having to register as commodity trading advisors ("CTAs"). The Commission has also been asked to address circumstances where a feedlot operator finances cattle or cattle feed purchases and is authorized to establish a hedge position in specified situations. The Commission has reviewed Advisory 88-1 in light of these requests and is hereby issuing revised interpretative guidelines, which incorporate and supplement Advisory 88-1.

The interpretative guidelines issued herewith by the Commission restate the analysis previously contained in Advisory 88-1, with several modifications. Scenarios 3 and 4 have been revised and two new scenarios have been added. The modifications of Scenarios 3 and 4 reflect that a custom feedlot operator may, in certain circumstances and in a manner incidental to its cash market business, provide advice with respect to hedging specified commodity interests without having to register as a CTA pursuant to Commission Rule 4.14(a)(1), 17 CFR 4.14(a)(1) (1989). Scenario 7 has been added to address the situation in which a feedlot operator is affiliated with a futures commission merchant ("FCM"). Scenario 8 addresses circumstances where a feedlot operator extends credit to a customer to purchase cattle or cattle feed pursuant to an agreement that provides for establishment of a hedge position in the event of a default by the customer.

Registration Guidelines for Feedlot Operators

The Commission is issuing the following guidelines in response to inquiries concerning the application of the Commodity Exchange Act (the "Act") and Commission regulations to

custom feedlot operators² ("feedlot operators"). These guidelines are intended to provide general guidance only and are not a substitute for analysis of the facts of a specific situation in light of the requirements of the Act and Commission regulations. The Commission and its staff will continue to provide case-by-case review as necessary to address specific fact situations not addressed by these guidelines.

Scenario 1 Feedlot Operator, Inc. ("FOI") offers to provide its customers, as an additional service to its other operations, with futures market hedging services.³ A customer wishing to take advantage of this service signs a power of attorney giving FOI authority to enter trades on the customer's behalf and the customer sends a check made out to FOI to cover the margin requirements. The trades are cleared on an omnibus basis by ABC Corp., a registered futures commission merchant ("FCM"), through an account titled "FOI Customer Omnibus Account," which includes the trades of all of FOI's customers who use FOI's hedging services.

FOI would be required to register under the Act as an FCM since it is engaged in soliciting or in accepting orders for futures trades (whether the orders are for hedging or speculative purposes is irrelevant) and it accepts money, securities or property to margin, guarantee or secure the trades. It is also irrelevant for these purposes whether FOI receives a separate fee specifically as payment for its hedging services. Any employee of FOI who is directly involved in soliciting or accepting orders, other than in a clerical capacity, or the supervision of any person so engaged would be required to register as associated persons of FOI. Because FOI would come within the definition of an FCM and would have to register as such, its advisory activities (entering futures trades pursuant to a power of attorney) would be deemed incidental to its FCM activities and FOI would not also have to register separately as a commodity trading advisor ("CTA").

Scenario 2 Same as Scenario 1, except that the customer does not send a check to FOI but FOI sends funds on

the customer's behalf to ABC Corp., with FOI retaining a security interest in the customer's cattle.

The result is the same as in 1 above. An extension of credit, in lieu of the acceptances of money, securities, or property as margin, also brings one within the definition of an FCM.

Scenario 3 Same as Scenario 1, except that the customer does not send a check to FOI but instead opens his own account on a fully-disclosed basis with ABC Corp. and sends his margin payments directly to ABC Corp.

Since FOI is not handling customer funds, it would not have to register as an FCM in this case. The question arises whether FOI's activities would require registration in another category, either as an introducing broker ("IB") or as a CTA. Although these two categories overlap to a certain extent, the Commission believes that if any registration category would be appropriate under this Scenario, it would be that of CTA and not IB because FOI would have a power of attorney from the customer and therefore would be considered to be directing trading. See 17 CFR 1.3(mm)(2)(ii) (1989). If FOI is not registered as an FCM or as an IB, its advisory activities would not be considered incidental to FCM or IB activities and the necessity for CTA registration must be evaluated in light of the factors set forth below.

Rule 4.14(a)(1)⁴ provides that a person is not required to register as a CTA if "it is a dealer, processor, broker, or seller in cash market transactions of any commodity (or any product thereof) and the person's commodity trading advice is solely incidental to the conduct of its cash market business." This exemption from CTA registration for persons providing commodity trading advice that is incidental to the conduct of a dealer, processor, broker or seller's cash market operations was originally adopted to exempt such persons from the requirement of CTA registration then applicable to persons rendering advice concerning the trading of cash commodities.⁵ However, the

¹ 17 CFR 4.14(a)(1) (1989).

² 43 FR 32291 (July 26, 1978). When originally adopted in 1978, the exemption for cash market dealers, processors, buyers and sellers was found in Rule 1.71, the predecessor of Rule 4.14(a)(1). At that time the definition of a "commodity trading advisor" set forth in section 2(a)(1)(A) of the Act included persons whose commodity advice concerned the value of cash commodities. 43 FR 32291 (July 26, 1978). Specifically, section 2(a)(1)(A) included within the CTA definition persons whose advice was directed "to the value of commodities, or as to the advisability of trading in any commodity for

Continued

¹ Scenarios 3 and 4 of Advisory 88-1 assumed that the feedlot operator received compensation or profit for its futures-related activities.

² A custom feedlot operator is a person who operates a "custom feedlot" as defined in rules promulgated under the Packers and Stockyards Act, 7 U.S.C. 181 et seq. (1982). The rules promulgated under the Packers and Stockyards Act define a custom feedlot to mean "any facility which is used in its entirety or in part for the purpose of feeding livestock for the accounts of others, but does not include feeding incidental to the sale or transportation of livestock." 9 CFR 201.2(k) (1989).

³ The futures market hedging services described herein may include both futures and exchange-traded options on futures.

Commission believes that the exemption may appropriately be applied to custom feedlot operators who in conjunction with their business activities as processors of cash commodities provide limited futures trading advice that is solely incidental to the conduct of such processing activities in the circumstances set forth below.

The Commission understands that feedlot operators engaged in custom feedlot services ordinarily do not take title to their customers' cattle. Such feedlot operators engage in processing services on behalf of their customers, i.e., feeding and preparing the customers' cattle for subsequent sale such that value is added to the cattle. In situations where the feedlot operator offers processing services relating to cattle without taking title to the cattle, the Commission believes that the custom feedlot operator is acting as a "processor" of a cash commodity or product thereof as that term is used in Rule 4.14(a)(1).

The Commission believes that extending the Rule 4.14(a)(1) exemption to custom feedlot operators who provide commodity trading advice that is solely incidental to, and is provided without charge in conjunction with, the primary processing services they provide to their feedlot customers would not be contrary to the public interest. The Commission believes that the trading advice provided may be characterized as incidental to the customer feedlot operator's cash market business if such advice is: (1) Provided solely to hedge the customer's cattle being fed at such

feedlot operator or to hedge grain purchases for the purpose of feeding such cattle; (2) not provided to customers other than customers employing the feedlot operator's processing services; (3) provided at *de minimis* cost to the feedlot operator; (4) provided at no extra charge to any of its customers, e.g., there should be no difference in the amount paid to the feedlot operator by different customers having the same volume of cattle processed through the feedlot if one customer uses advisory services of the feedlot operator and another customer does not; (5) provided without the feedlot operator soliciting customers for its advisory services or holding itself out generally to the public as a CTA; and (6) provided without restriction as to the customer's choice of FCM.

If FOI does not offer its futures market hedging services in accordance with the foregoing criteria, then FOI would be required to register as a CTA and any of its employees who solicit customers to open discretionary accounts with FOI or supervise any person so engaged would be required to register as associated persons of that CTA. Feedlot operators which the Commission would exempt from registration as CTAs by extension of Rule 4.14(a)(1) would remain subject to the anti-fraud provisions applicable to CTAs in section 40 of the Act, 7 U.S.C. 60 (1982).

Scenario 4 Same as Scenario 3, except that FOI does not have a power or attorney from the customer, but merely gives the customer hedging advice and the customer places the orders and makes the actual futures trading decisions.

Assuming that FOI's futures market hedging services are offered as set forth in Scenario 3 such that FOI would qualify for the exemption from CTA registration by the extension of Rule 4.14(a)(1) discussed herein, FOI would not be required to register as a CTA. However, FOI would be required to register as a CTA if such services were not solely incidental to FOI's cash business. Since no discretionary trading is involved, none of FOI's employees would be required to register as associated persons.

Scenario 5 Same as Scenario 1, except that the customer opens his own account on a fully-disclosed basis with ABC Corp., does not give FOI authority to enter trades through a power of attorney, but does give FOI his futures orders and a check made payable to ABC Corp. for transmission to ABC Corp.

In this case, FOI would be required to register as an IB.⁶ Unlike an FCM, an IB may solicit or accept futures orders but cannot accept in its own name money, securities or property (or extend credit) to margin, guarantee or secure futures trades. The mere fact that the margin check is transmitted by FOI would not require FOI to register as an FCM, provided the check is not drawn in FOI's name and FOI complies with the Commission's rules concerning the deposit of such checks in a "one-way bank account." See Commission Rule 1.57(c), 17 CFR 1.57(c) (1989). Employees of FOI who deal with customers with respect to their futures trades other than in a clerical capacity would have to register as associated persons of an IB.

Scenario 6 FOI does not advertise or promote futures market hedging services, but one of its customers tells FOI that he has decided to hedge his feeder cattle in the futures market and asks FOI to recommend a broker. FOI mentions the name of ABC Corp. All futures-related business is conducted directly between the customer and ABC Corp.

If FOI were to be compensated by ABC Corp. or by the customer for this "referral" on a per-trade basis for each trade entered by the customer, FOI would have to register as an IB. If FOI were to be compensated for providing the name of ABC Corp. by means of a lump-sum "finder's fee" payment by either ABC Corp. or by the customer, FOI would be required to register either as an IB or as a CTA. If FOI were to register as an IB, any employee of FOI directly involved in soliciting or accepting orders, other than in a clerical capacity, would have to register as an associated person. If this is FOI's only activity related to the futures markets and FOI receives no compensation from ABC Corp. and no compensation from the customer beyond its normal feedlot compensation, FOI need not register under the Act.

Scenario 7 Same as Scenario 6, except that FOI maintains an affiliated commodity brokerage firm ("CBF") as a separately incorporated business entity that is operated separately from FOI's

⁶There are two types of IB, a guaranteed IB and an independent IB. A guaranteed IB enters into a guarantee agreement with the FCM carrying its customers' accounts and does not have to raise its own capital. A guaranteed IB must meet the requirements set forth in Rule 1.17(a)(2)(ii), 17 CFR 1.17(a)(2)(ii) (1989). An independent IB must raise its own capital in order to meet the minimum financial requirement of \$20,000 of adjusted net capital. See Rule 1.17(a)(1)(ii), 17 CFR 1.17(a)(1)(ii) (1989).

future delivery on or subject to the rules of any contract market." 7 U.S.C. 2 (1982). To qualify for relief from registration as a CTA under the exemption for cash market operations set forth in the original Rule 1.71, the person's advice had to be "(a) directed solely to cash commodity transactions (as distinguished from commodity futures, commodity option or leverage transactions) and (b) incidental to the person's business." 43 FR 32291, 32292 (July 26, 1978). Rule 1.71 subsequently was incorporated into Rule 4.14(a)(1). 46 FR 26004, 26007 (May 8, 1981). In 1982, however, the statutory definition of a CTA was amended to delete from the CTA definition in section 2(a)(1)(A) the phrase "the value of commodities." See Futures Trading Act of 1982, Public Law No. 97-444, § 201, 96 Stat. 2294 (1982). Section 2(a)(1)(A) was also amended to provide that the Commission, by rule or regulation, may include within the CTA definition any person advising as to the value of commodities or issuing reports or analyses concerning commodities if the Commission determines that such rule or regulation will effectuate the purposes of the provision. The exemption from CTA registration in Rule 4.14(a)(1) for persons providing commodity trading advice that is solely incidental to dealer, processor and other specified cash market activities was not modified following enactment of the 1982 statutory amendments.

cash market activities. CBF is managed independently of the cattle feeding segment of the business and is properly registered under the Act as an FCM. If FOI does not solicit customers or business for CBF, FOI will not be required to register as an IB. In determining whether FOI has an IB relationship with CBF, the Commission will consider the entire business relationship between FOI and CBF.

Scenario 8 Feedlot operators may extend credit, either directly or as intermediaries for a finance company, to interested customers wishing to finance cattle or feed purchases. Where a lending agreement, in connection with the financing of the customer's cattle or feed purchases, between FOI and an FOI customer provides FOI with authority to establish a hedge position in the event of the customer's default under the agreement, the agreement typically provides that the resulting position is owned by and is held for the benefit of the customer. Such agreements generally provide the feedlot operator authority to establish a futures position in the event of default by the customer in order to protect the value of the collateral posted to secure the loan. The customer provides written power of attorney to the feedlot operator to establish a futures position pursuant to the terms of the financing agreement. The profits, losses, costs and margin payments resulting from positions taken pursuant to such an agreement are applied to the account of the customer. The hedge position may be established and maintained only after good faith efforts by the feedlot operator to provide the debtor an opportunity to cure the default prior to establishment of the position.

The authority to establish a futures position held by the feedlot operator in the circumstances set forth above is defined by the terms of the written financing agreement between FOI and the customer. Such authority exists only after notice of the default has been given the customer and the customer has been afforded a reasonable opportunity to cure the default. Although the terms of such agreements provide that the customer is responsible for the margin payments, expenses and losses incurred in connection with the futures position established by FOI, the position is established solely to protect the value of the collateral posted by the customer. The feedlot operator, acting pursuant to such an agreement, may only establish such hedge positions as are necessary to protect the value of the customer's collateral. Therefore, although held for the benefit of the customer, such

position is intended to support FOI's ability to recover its loan. Accordingly, the commission will adopt a no-action position such that it will not take enforcement action against FOI for failing to register in any capacity provided that the authority to establish the hedge position and the customer's responsibility for margin payments, expenses and losses incurred in connection with the position are expressly stated in the lending agreement; the customer provides a limited power of attorney to the lender that grants authority to the lender to establish a futures position only in the event of default by the customer and for purposes of hedging to protect the feedlot operator's interest in the collateral posted by the customer; and no profit accrues to the feedlot operator.

A feedlot operator as described herein remains subject to all other applicable provisions of the Act and the Commission's regulations thereunder—e.g., to the general anti-fraud provisions of sections 4b and 4c, 7 U.S.C. 6b and 6c (1982) of the Act and the reporting requirements for traders as set forth in parts 15, 18 and 19 of the Commission's regulations, 17 CFR parts 15, 18, and 19 (1989).

The Commission welcomes the written views of any interested persons concerning these guidelines.

Issued in Washington DC, on January 25, 1990, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 90-2099 Filed 1-30-90; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by the Upjohn Co. The supplement adds a new claim for the use of lincomycin hydrochloride in the drinking water of broiler chickens to control necrotic enteritis and deletes the existing tolerance for residues of lincomycin in chickens.

EFFECTIVE DATE: January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Nelson S. Chou, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, is the sponsor of NADA 111-636 which currently provides for the use of lincomycin hydrochloride soluble powder in the drinking water of swine for the treatment of dysentery. The firm has submitted a supplemental NADA seeking: (1) Approval of a new claim for the use of lincomycin hydrochloride soluble powder in the drinking water of broiler chickens to control necrotic enteritis caused by *Clostridium perfringens* and; (2) deletion of the existing tolerance for residues of lincomycin in chickens. The supplement is approved and 21 CFR 520.1263c and 556.360 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, the agency is further amending § 556.360 by deleting the tolerance for lincomycin residues in milk because there is no approved NADA for the use of lincomycin in dairy cattle.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR part 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1263c is amended by revising paragraph (d) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble power.

* * * * *

(d) *Conditions of use*—(1) It is used in drinking water for swine as follows:

(i) *Amount.* 250 milligrams per gallon.

(A) *Dosage.* 3.8 milligrams per pound of body weight per day.

(B) *Indications for use.* Treatment of swine dysentery (bloody scours).

(C) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. Not for use in swine weighing more than 250 pounds. Do not slaughter swine for 6 days following last treatment.

(ii) [Reserved]

(2) It is used in drinking water for broiler chickens as follows:

(i) *Amount.* 64 milligrams per gallon.

(A) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

(B) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

(ii) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. Section 556.360 is revised to read as follows:

§ 556.360 Lincomycin.

(a) *Swine.* A tolerance of 0.1 part per million is established for negligible residues in the edible tissues.

(b) *Chickens.* A tolerance for residues of lincomycin in chickens is not required.

Dated: January 23, 1990.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 90-2098 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Fair Housing and Equal Opportunity

24 CFR Part 103

[Docket No. R-90-1465; FR-2725-F-01]

Fair Housing Complaint Processing; Miscellaneous Revisions

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations governing the complaint processing procedure under the Fair Housing Act. These regulations require the Assistant Secretary for Fair Housing and Equal Opportunity to notify the aggrieved person and the respondent, by certified mail or personal service, of reasons for delays in the investigation of complaints beyond 100 days from the filing of a complaint (or a notice or reactivation under § 103.115). 24 CFR 103.225. The complaint processing procedure also requires the Assistant Secretary to notify the aggrieved person and the respondent, by certified mail or personal service, of reasons for the delay in issuing a determination whether reasonable cause exists to believe that a discriminatory housing practice has occurred or is about to occur. Such determinations are subject to the same 100-day time requirement. 24 CFR 103.400. This final rule allows either the Assistant Secretary or another appropriate official within HUD to notify the aggrieved person and the respondent of the delay in completing the processing of a complaint. This final rule also provides that the notification will be sent by regular United States mail, rather than by certified mail or personal service.

HUD's complaint processing procedures also require that if the General Counsel determines that no reasonable cause exists, the Department

shall make public disclosure of the dismissal by issuance of a press release, except that the respondent may request that no release be made, 24 CFR 103.400. This final rule permits public disclosure either through the issuance of a press release or through other appropriate methods of public disclosure.

The purpose of this rule is to simplify and streamline certain procedural aspects of HUD's Fair Housing regulations.

EFFECTIVE DATE: March 2, 1990.

FOR FURTHER INFORMATION CONTACT:

Roy Rodriguez (202) 755-5518, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC, 20410-0500. (The telephone number set forth above is not a toll-free number.) The toll-free TDD number is 1-800-543-6294 for impaired persons who may wish to use this number for information or assistance.

Background

Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601-3619) made it unlawful to discriminate in any aspect relating to the sale, rental or financing of dwellings or in the provision of brokerage services or facilities in connection with the sale or rental of a dwelling because of race, color, religion, sex, or national origin. Under the provisions of title VIII, persons who believed that they had been subjected to, or were about to be subjected to a discriminatory housing practice could file a complaint with the Secretary of Housing and Urban Development. Title VIII required the Department of Housing and Urban Development to investigate each complaint and, where the Department determined to resolve the matters raised in a complaint, to engage in informal efforts to conciliate the issues in the complaint. Where these informal efforts to conciliate a case were unsuccessful, however, title VIII did not provide the Secretary with any administrative mechanism for redressing acts of discrimination against an individual. In addition, while the Secretary could refer a case involving a pattern or practice of discrimination to the Attorney General for the initiation of a civil action, Federal courts did not award individual relief to the victims of discrimination in such cases.

The Fair Housing Amendments Act of 1988 (Pub. L. 100-430, 102 Stat. 1626 (1988), approved September 13, 1988), was enacted to strengthen the administrative enforcement provision of title VIII, to add prohibitions against discrimination in housing on the basis of

handicap and familial status, and to provide for the award of monetary damages where discriminatory housing practices are found. The amended Fair Housing Act became effective on March 12, 1989. HUD's final rule implementing the Fair Housing Act was published on January 23, 1989 (54 FR 3232) and also became effective on March 12, 1989.

Sections 810(a)(1)(B)(iv) and 810(a)(1)(C) of the Fair Housing Act provide that HUD must complete investigations within 100 days after the filing of a complaint (or, when a complaint has been referred to a substantially equivalent State or local agency and later reactivated by HUD, within 100 days after service of the notification of reactivation), unless it is impracticable to do so. If the investigation cannot be completed within this time limit, HUD is required to notify the aggrieved person and the respondent in writing of the reasons for the delay. Section 810(g)(1) requires HUD, within the same 100-day period, to make a determination whether reasonable cause exists to believe that a discriminatory housing practice has occurred or is about to occur, and to provide notification of the reasons for any delay. HUD's regulation provides that the Assistant Secretary for Fair Housing and Equal Opportunity shall make these notifications and shall do so by sending notices by certified mail or personal service. (24 CFR 103.225 and 24 CFR 103.400(c)(2).)

This final rule provides for greater flexibility with regard to which officials within the Department may notify the complainant and respondent of delays. At times it may be convenient for the Assistant Secretary for Fair Housing and Equal Opportunity to send the notice. In other circumstances, depending upon the stage of complaint processing within the Department, it may be more convenient for another HUD official to send the notice. Allowing other appropriate officials aside from the Assistant Secretary (e.g., the Deputy Assistant Secretary for Compliance and Enforcement) to send the notification of delay will provide greater flexibility, convenience, expediency, and simplicity, and will ease the administrative burden on the Department.

This final rule will also permit HUD to notify the complainant and respondent of delays by regular United States mail, rather than by certified mail or personal service. There is no statutory requirement that service be by certified mail or personal service. Sections 810 and 812 of the Act simply require written notification. The use of regular

mail will be less expensive and will provide greater convenience and simplicity.

Section 810(g)(3) of the Fair Housing Act provides that if the Secretary determines that no reasonable cause exists to believe that a discriminatory housing practice has occurred or is about to occur, the Secretary shall promptly dismiss the complaint and shall make public disclosure of each such dismissal. The existing regulation provides that public disclosure of the dismissal shall be by issuance of a press release. 24 CFR 103.400(a)(ii).

This final rule amends the complaint processing regulation to allow greater flexibility with regard to the method of making public disclosure of dismissals. Alternative methods of public disclosure exist that meet the requirements of the statute. (For example, the Department could post notices of no cause findings at the field office which investigated the complaint.) Permitting alternative methods of public disclosure will afford greater flexibility, convenience, expediency, and simplicity, and will ease the administrative burden. This amendment is consistent with provisions governing the public disclosure of conciliation agreements under 24 CFR 103.330(b). This section provides that conciliation agreements shall be made public, but does not specifically require any particular method of public disclosure.

The changes in this final rule are technical, procedural changes which only affect operations within HUD. This rule does not affect substantive rights. During the development of regulations implementing the Fair Housing Amendments Act, *see* 54 FR 3232 (published January 23, 1989), virtually no comments were received concerning matters affected by this final rule. *See* 54 FR 3232-3282. For these reasons, the Department finds that notice and comment are unnecessary.

Findings and Certification

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours (7:30 a.m. to 5:30 p.m.) in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW., Washington, DC 20410.

This rule does not constitute a "major rule" as that term is defined in section

1(d) of the Executive Order 12291 on Federal Regulations issued by the President on February 17, 1981. An analysis of the rule indicates that it does not (1) have an annual effect on the economy of \$100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic region; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In accordance with 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule is a technical, procedural change which only affects operations within HUD. The rule does not affect substantive rights.

The General Counsel, as the Designated Official under Executive Order No. 12606—The Family, has determined that this rule, if implemented, would have no significant impact on the family. The rule is a technical, procedural change which only affects operations within HUD. The rule does not affect substantive rights.

The General Counsel, as the Designated Official under section 6(a) of Executive Order No. 12612—Federalism, has determined that this rule, if implemented, would have no significant impact on federalism. The rule is a technical, procedural change which only affects operations within HUD. The rule does not affect substantive rights.

This rule was not listed in the Department's Semiannual Agenda of Regulations published October 30, 1989 (54 FR 44702).

(The Catalog of Federal Domestic Assistance program number and title is 14.400 Equal Opportunity in Housing)

List of Subjects in 24 CFR Part 103

Administrative practice and procedure, Fair housing.

Accordingly, title 24 of the Code of Federal Regulations is amended as follows:

PART 103—FAIR HOUSING—COMPLAINT PROCESSING

1. The authority citation for part 103 continues to read as follows:

Authority: Title VIII, Civil Rights Act of 1968, 42 U.S.C. 3600-3620; sec. 7(d), Department of HUD Act (42 U.S.C. 3535(c)).

2. Section 103.225 is revised to read as follows:

§ 103.225 Completion of investigation

The investigation will remain open until the reasonable cause determination is made under § 103.400, or a conciliation agreement is executed and approved under § 103.310. Unless it is impracticable to do so, the Assistant Secretary will complete the investigation of the alleged discriminatory housing practice within 100 days of the filing of the complaint (or where the Assistant Secretary reactivates the complaint, within 100 days after service of the notice of reactivation under § 103.115). If the Assistant Secretary is unable to complete the investigation within the 100-day period, HUD will notify the aggrieved person and the respondent, by mail, of the reasons for the delay.

3. Paragraphs (a)(1)(ii) and (c)(2) of § 103.400 are revised to read as follows:

§ 103.400 Reasonable cause determination.

(a) * * *

(1) * * *

(ii) If the General Counsel determines that no reasonable cause exists, the General Counsel shall: issue a short and plain written statement of the facts upon which the General Counsel has based the no reasonable cause determination; dismiss the complaint; notify the aggrieved person and the respondent of the dismissal (including the written statement of facts) by certified mail or personal service; and make public disclosure of the dismissal. The respondent may request that no public disclosure be made. Notwithstanding such a request, the fact of the dismissal, including the names of the parties, shall be public information available on request.

* * *

(c) * * *

(2) If the General Counsel is unable to make the determination within the 100-day period specified in paragraph (c)(1) of this section, HUD will notify the aggrieved person and the respondent, by mail, of the reasons for the delay.

Dated: January 8, 1990.

Gordon Mansfield,

Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. 90-2132 Filed 1-30-90; 8:45 am]

BILLING CODE 4210-28-M

Office of the Secretary

24 CFR Parts 812, 813, 885, 912 and 913

[Docket No. R-90-1418; FR-2476-C-03]

RIN 2502-AE47

Loans for Housing for the Elderly or Handicapped; Section 202; Projects for Nonelderly Handicapped Families and Individuals; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule; Correction.

SUMMARY: On June 20, 1989 (54 FR 25960), the Department published in the *Federal Register*, a final rule that, pursuant to section 202 of the Housing Act of 1959, authorized HUD to provide direct loans for the development of projects to serve elderly or handicapped families and individuals. The purpose of this document is to correct the amendatory language for "§ 885.5 Definitions" regarding the definition "Field Office". The amendatory language published in the final rule indicated that the definition "Field Office" was to be added. Since the definition already exists in title 24 of the Code of Federal Regulations, the amendatory language should have indicated that the definition for "Field Office" was being revised.

EFFECTIVE DATE: August 4, 1989.

FOR FURTHER INFORMATION CONTACT:

Margaret Milner, Office of Policy, Financial Management and Administration, Room 9106, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone (202) 755-3287 or 755-8135. The TDD number is 755-6781. (These are not toll-free numbers.)

Accordingly, in FR Doc. 89-14435, published in the *Federal Register* of June 20, 1989 (54 FR 25960), 24 CFR part 885 is amended by correcting the amendatory language for § 885.5 Definitions to read as follows:

PART 885—LOANS FOR HOUSING FOR THE ELDERLY OR HANDICAPPED

1. The authority citation for 24 CFR part 885 continues to read as follows:

Authority: Sec. 202, Housing Act of 1959 (12 U.S.C. 1701q); sec. 8, United States Housing Act of 1937 (42 U.S.C. 1437f); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

§ 885.5 [Amended]

2. On page 25980, in the third column, in item 9, the amendatory language for § 885.5 Definitions is corrected from "* * *" and definitions for "Elderly Family", "Field Office", "Handicapped Family", "Independent Public

Accountant" and "Nonelderly Handicapped Families" are added * * *, to read "* * * "Field Office", "Handicapped person" and "Housing and Related Facilities" are revised; and definitions for "Elderly Family", "Handicapped Family", "Independent Public Accountant" and "Nonelderly Handicapped Families" are added * * *".

Dated: January 24, 1990.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 90-2126 Filed 1-30-90; 8:45 am]

BILLING CODE 4210-32-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[T.D. 8287]

RIN 1545-AM56

Treatment of Certain Losses Attributable to Periods After October 31 of a Taxable Year of a Regulated Investment Company

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document provides temporary regulations relating to the treatment by a regulated investment company of a net capital loss, a net long-term capital loss, or a net foreign currency loss attributable to periods after October 31 of a taxable year. The applicable tax law was amended by the Tax Reform Act of 1986 and by the Technical and Miscellaneous Revenue Act of 1988. These regulations provide guidance to regulated investment companies as to the proper manner of determining taxable income, earnings and profits, and the amount that may be designated as capital gain dividends for a taxable year. The text of the temporary regulations set forth in this document also serves as the text of the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the *Federal Register*.

EFFECTIVE DATE: These regulations are effective for taxable years of regulated investment companies ending after October 31, 1987.

FOR FURTHER INFORMATION CONTACT:

Lauren G. Shaw of the Office of Assistant Chief Counsel (Financial Institutions and Products), Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224

(Attention: CC:FI&P:2) or telephone 202-566-3828 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collections of information contained in these regulations have been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number 1545-1094. The estimated average annual burden associated with the collections of information in these regulations is fifteen minutes per respondent.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances.

For further information concerning these collections of information, and where to submit comments on these collections of information, the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the Federal Register.

Background

This document amends the Income Tax Regulations (26 CFR part 1) under section 852 of the Internal Revenue Code of 1986 to reflect certain amendments made to the Code by the Tax Reform Act of 1986 (Pub. L. 99-514; 100 Stat. 2085) ("1986 Act") and by the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647; 102 Stat. 3342) ("TAMRA"). These amendments to the regulations reflect the addition of section 852(b)(8) to the Code and the amendments made to sections 852(b)(3)(C) and 852(c) of the Code by sections 651(b)(2) and (3) of the 1986 Act and sections 1006(1), (3), (4), and (7) of TAMRA.

These recent additions and amendments to the Code are designed to improve the coordination between the income tax provisions applicable to RICs and the provisions of new section 4982, which imposes an excise tax on a RIC which fails to distribute a certain amount of its income. The principal difficulty in coordinating the provisions is that section 4982 generally requires a RIC to use a 12-month period ending on

October 31 in measuring its capital gains and losses and foreign currency gains and losses for excise tax purposes regardless of the accounting period the RIC uses in computing its taxable income. The recent Code changes provide for adjustments to a RIC's taxable income to take into account the October 31 excise tax closing date. Section 4982(e)(4) permits a RIC using a taxable year ending November 30 or December 31 to elect to use its taxable year for purposes of the excise tax rather than the October 31 closing date. The special income tax adjustments therefore do not apply to a RIC making the section 4982(e)(4) election because the same period is used for both income tax and excise tax purposes.

Section 852(b)(3)(C) provides that, for purposes of determining the amount a RIC may designate as capital gain dividends for a taxable year to which an election under section 4982(e)(4) does not apply, the amount of the RIC's net capital gain shall be determined without regard to any net capital loss or net long-term capital loss attributable to the period after October 31 of the taxable year (the "post-October period"), and any such loss shall be treated as arising on the first day of the next taxable year (the "succeeding year"). Section 852(b)(3)(C) also provides that, to the extent set forth in regulations, these rules shall apply for purposes of determining a RIC's taxable income.

Section 852(b)(8) provides that, to the extent provided in regulations, the taxable income of a RIC for a taxable year to which an election under section 4982(e)(4) does not apply shall be computed without regard to any net foreign currency loss attributable to its post-October period, and any such loss shall be treated as arising on the first day of the succeeding year.

Section 852(c)(1) provides that any amount that is not allowable as a deduction in computing a RIC's taxable income for a taxable year does not reduce the RIC's earnings and profits for that year (although such amount may reduce its accumulated earnings and profits). A RIC's earnings and profits for a taxable year are thus determined without regard to any net capital loss, net long-term capital loss, or net foreign currency loss not included in computing the RIC's taxable income for that taxable year. In addition, section 852(c)(2) provides that, with respect to certain distributions made in a calendar year, a RIC's earnings and profits are determined without regard to any net capital loss or net foreign currency loss after October 31 of that year, adjusted as provided by regulations.

Explanation of the regulations

The regulations provide guidance relating to the determination of the amount that may be designated as capital gain dividends and to the determination of earnings and profits by a RIC having a net capital loss, a net long-term capital loss, or a net foreign currency loss attributable to the post-October period of a taxable year.

In addition, the regulations provide procedures by which a RIC may elect to defer part or all of a net capital loss, a net long-term capital loss, or a net foreign currency loss attributable to its post-October period to the succeeding year for purposes of determining its taxable income. The regulations also provide guidance relating to the proper calculation of taxable income and earnings and profits for the years affected.

Section 1.852-11T(c) of the regulations defines the term "post-October capital loss" to mean any net capital loss attributable to sales or exchanges after October 31 of a taxable year or, if there is no such net capital loss, any net long-term capital loss attributable to that period. In addition, § 1.852-11T(d)(1) defines the term "post-October currency loss" to mean any net foreign currency loss that is properly attributable to transactions after October 31 of a taxable year.

Section 1.852-11T(e) of the regulations provides that, for purposes of determining the amount a RIC may designate as capital gain dividends for a taxable year, any post-October capital loss for that year is disregarded. The post-October capital loss is treated as arising on the first day of the succeeding year.

Section 1.852-11T(f)(1) of the regulations provides that a RIC may elect to compute its taxable income for a taxable year without regard to part or all of its post-October capital loss or post-October currency loss for that year. Under § 1.852-11T(f)(4), any part of a post-October capital or currency loss for a taxable year that a RIC elects to defer under § 1.852-11T(f)(1) is treated as arising on the first day of the succeeding year. Thus, that part of any post-October capital or currency loss for a taxable year that a RIC elects to defer under § 1.852-11T(f)(1) will be disregarded in computing the RIC's taxable income for that year, but will be taken into account in computing the RIC's taxable income for the succeeding year.

Under § 1.852-11T(f)(5), an election to defer a post-October capital or currency loss under § 1.852-11T(f)(1) for purposes

(b) *Scope*—(1) *In general*. This section prescribes the manner in which a regulated investment company must treat a post-October capital loss (as defined in paragraph (c) of this section) or a post-October currency loss (as defined in paragraph (d)(1) of this section) for purposes of determining its taxable income, its earnings and profits, and the amount that it may designate as capital gain dividends for the taxable year in which the loss is incurred and the succeeding taxable year (the "succeeding year").

(2) *Limitation on application of section*. This section shall not apply to any post-October capital loss or post-October currency loss of a regulated investment company attributable to a taxable year for which an election is in effect under section 4982(e)(4) of the Code with respect to the company.

(c) *Post-October capital loss defined*. For purposes of this section, the term "post-October capital loss" means—

(1) Any net capital loss attributable to sales or exchanges after October 31 of a taxable year; or

(2) If there is no such net capital loss, any net long-term capital loss attributable to sales or exchanges after October 31 of a taxable year. The amount of any net capital loss or any net long-term capital loss attributable to sales or exchanges after October 31 of a taxable year shall be determined in accordance with general tax law principles by treating the period beginning on November 1 of the taxable year of the regulated investment company and ending on the last day of such taxable year as though it were the taxable year of the regulated investment company.

(d) *Post-October currency loss defined*. For purposes of this section—

(1) *Post-October currency loss*. The term "post-October currency loss" means any net foreign currency loss attributable to section 988 transactions that are properly attributable to the portion of the regulated investment company's taxable year after October 31.

(2) *Net foreign currency loss*. The term "net foreign currency loss" means the excess of foreign currency losses over foreign currency gains.

(3) *Foreign currency gain or loss*. The terms "foreign currency gain" and "foreign currency loss" have the same meaning as provided in section 988(b).

(e) *Limitation on capital gain dividends*—(1) *In general*. For purposes of determining the amount a regulated investment company may designate as capital gain dividends for a taxable year, the amount of net capital gain for the taxable year shall be determined

without regard to any post-October capital loss for such year.

(2) *Amount taken into account in current year*—(i) *Net capital loss*. If the post-October capital loss referred to in paragraph (e)(1) of this section is a post-October capital loss as defined in paragraph (c)(1) of this section, the net capital gain of the company for the taxable year in which the loss arose shall be determined without regard to any capital gains or losses (both long-term and short-term) from sales or exchanges after October 31 of the taxable year.

(ii) *Net long-term capital loss*. If the post-October capital loss referred to in paragraph (e)(1) of this section is a post-October capital loss as defined in paragraph (c)(2) of this section, the net capital gain of the company for the taxable year in which the loss arose shall be determined without regard to any long-term capital gain or loss from sales or exchanges after October 31 of the taxable year.

(3) *Amount taken into account in succeeding year*. If a regulated investment company has a post-October capital loss (as defined in paragraph (c)(1) or (c)(2) of this section) for any taxable year, then, for purposes of determining the amount the company may designate as capital gain dividends for the succeeding year, the net capital gain for the succeeding year shall be determined by treating all gains and losses taken into account in computing the post-October capital loss as arising on the first day of the succeeding year.

(f) *Regulated investment company may elect to defer certain losses for purposes of determining taxable income*—(1) *In general*. A regulated investment company may elect, in accordance with the procedures of paragraph (i) of this section, to compute its taxable income for a taxable year without regard to part or all of any post-October capital loss or post-October currency loss for that year.

(2) *Effect of election in current year*. The taxable income of a regulated investment company for a taxable year to which an election under paragraph (f)(1) of this section applies shall be computed without regard to that part of any post-October capital loss or post-October currency loss to which the election applies.

(3) *Amount of loss taken into account in current year*—(i) *If entire amount of net capital loss deferred*. If a regulated investment company elects, under paragraph (f)(1) of this section, to defer the entire amount of a post-October capital loss as defined in paragraph (c)(1) of this section, the taxable income of the company for the taxable year in

which the loss arose shall be determined without regard to any capital gains or losses (both long-term and short-term) from sales or exchanges after October 31 of the taxable year.

(ii) *If part of net capital loss deferred*—(A) *In general*. If a regulated investment company elects, under paragraph (f)(1) of this section, to defer less than the entire amount of a post-October capital loss as defined in paragraph (c)(1) of this section, the taxable income of the company for the taxable year in which the loss arose shall be determined by including an amount of capital loss from sales or exchanges after October 31 of the taxable year equal to the amount of the post-October capital loss that is not deferred. No amount of capital gain from sales or exchanges after October 31 of the taxable year shall be taken into account in the determination.

(B) *Character of capital loss not deferred*. The capital loss includible in the taxable income of the company under this paragraph (f)(3)(ii) for the taxable year in which the loss arose shall consist first of any short-term capital losses to the extent thereof, and then of any long-term capital losses, attributable to sales or exchanges after October 31 of the taxable year.

(iii) *If entire amount of net long-term capital loss deferred*. If a regulated investment company elects, under paragraph (f)(1) of this section, to defer the entire amount of a post-October capital loss as defined in paragraph (c)(2) of this section, the taxable income of the company for the taxable year in which the loss arose shall be determined without regard to any long-term capital gains or losses from sales or exchanges after October 31 of the taxable year.

(iv) *If part of net long-term capital loss deferred*. If a regulated investment company elects, under paragraph (f)(1) of this section, to defer less than the entire amount of a post-October capital loss as defined in paragraph (c)(2) of this section, the taxable income of the company for the taxable year in which the loss arose shall be determined by including an amount of long-term capital loss from sales or exchanges after October 31 of the taxable year equal to the amount of the post-October capital loss that is not deferred. No amount of long term capital gain from sales or exchanges after October 31 of the taxable year shall be taken into account in the determination.

(v) *If entire amount of post-October currency loss deferred*. If a regulated investment company elects, under paragraph (f)(1) of this section, to defer the entire amount of a post-October

currency loss, the taxable income of the company for the taxable year in which the loss arose shall be determined without regard to any foreign currency gains or losses attributable to transactions after October 31 of the taxable year.

(vi) *If part of post-October currency loss deferred.* If a regulated investment company elects, under paragraph (f)(1) of this section, to defer less than the entire amount of a post-October currency loss, the taxable income of the company for the taxable year in which the loss arose shall be determined by including an amount of foreign currency loss attributable to transactions after October 31 of the taxable year equal to the amount of the post-October currency loss that is not deferred. No amount of foreign currency gain attributable to transactions after October 31 of the taxable year shall be taken into account in the determination.

(4) *Amount of loss taken into account in succeeding year.* If a regulated investment company has a post-October capital loss or a post-October currency loss for any taxable year and an election under paragraph (f)(1) is made for that year, then, for purposes of determining the taxable income of the company for the succeeding year, all capital gains and losses taken into account in determining the post-October capital loss, and all foreign currency gains and losses taken into account in determining the post-October currency loss, that are not taken into account under the rules of paragraph (f)(3) of this section in determining the taxable income of the a regulated investment company for the taxable year in which the loss arose shall be treated as arising on the first day of the succeeding year.

(5) *Effect on gross income.* An election by a regulated investment company to defer any post-October capital loss or any post-October currency loss for a taxable year under paragraph (f)(1) of this section shall not affect the amount of the gross income of such company for such taxable year (or the succeeding year) for purposes of section 851(b) (2) or (3).

(g) *Earnings and profits—(1) General rule.* The earnings and profits of a regulated investment company for a taxable year are determined without regard to any post-October capital loss or post-October currency loss for that year. If a regulated investment company distributes with respect to a calendar year amounts in excess of the limitation described in the succeeding sentence, then, with respect to those excess amounts, for the taxable year with respect to which the amounts are distributed, the earnings and profits of

the company are computed without regard to the preceding sentence. The limitation described in this sentence is the amount that would be the required distribution for that calendar year under section 4982 if "100 percent" were substituted for each percentage set forth in section 4982(b)(1).

(2) *Special Rule—Treatment of losses that are deferred for purposes of determining taxable income.* If a regulated investment company elects to defer, under paragraph (f)(1) of this section, any part of a post-October capital loss or post-October currency loss arising in a taxable year, then, for both the taxable year in which the loss arose and the succeeding year, both the earnings and profits and the accumulated earnings and profits of the company are determined as if the part of the loss so deferred had arisen on the first day of the succeeding year.

(h) *Examples.* The provisions of paragraphs (e), (f), and (g) of this section may be illustrated by the following examples. For each example, assume that X is a regulated investment company that computes its income on a calendar year basis, and that no election is in effect under section 4982(e)(4).

Example (1). X has a \$25 net foreign currency gain, a \$60 net short-term capital loss, and a \$75 net long-term capital gain for the post-October period of 1988. X has no post-October currency loss and no post-October capital loss for 1988, and this section does not apply.

Example (2). X has the following capital gains and losses from sales or exchanges during the periods indicated:

	Long-term	Short-term
01/01 to 10/31/88	115 (15) 100	80 (20) 60
11/01 to 12/31/88	75 (150) (75)	150 (50) 100
01/01 to 10/31/89	30 (5) 25	40 (20) 20
11/01 to 12/31/89	35 (0) 35	100 (50) 50

X has a post-October capital loss of \$75 for its 1988 taxable year due to a net long-term capital loss for the post-October period of 1988. X does not make an election under paragraph (f)(1) of this section.

(i) *Capital gain dividends.* X may designate up to \$100 as a capital gain dividend for 1988 because X must disregard the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988 in

computing its net capital gain for this purpose. In computing its net capital gain for 1988 for the purposes of determining the amount it may designate as a capital gain dividend for 1988, X must take into account the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988 in addition to the long-term and short-term capital gains and losses for 1988. Accordingly, X may not designate any amount as a capital gain dividend for 1988.

(ii) *Taxable income.* X must include the \$75 long-term capital gain and the \$150 long-term capital loss for its post-October period of 1988 in its taxable income for 1988 because it did not make an election under paragraph (f)(1) of this section for 1988. Accordingly, X's taxable income for 1988 will include a net capital gain of \$25 and a net short-term capital gain of \$160. X's taxable income for 1989 will include a net capital gain of \$60 and a net short-term capital gain of \$70.

(iii) *Earnings and profits.* X must determine its earnings and profits for 1988 without regard to the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988. X must, however, include the \$75 long-term capital gain and \$150 long-term capital loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. Thus, X includes \$260 of capital gain in its earnings and profits for 1988, includes \$165 in its accumulated earnings and profits for 1988, and includes \$130 of capital gain in its earnings and profits for 1989.

Example (3). Same facts as example (2), except that X elects to defer the entire \$75 post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) *Capital gain dividends.* Same result as in example (2).

(ii) *Taxable income.* X must compute its taxable income for 1988 without regard to the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988 because it made an election to defer the entire \$75 post-October capital loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net capital gain of \$100 and a net short-term capital gain of \$160. X must include the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X's taxable income for 1989 will include a net long-term capital loss of \$15 and a net short-term capital gain of \$70.

(iii) *Earnings and profits.* For 1988, X must determine both its earnings and profits and its accumulated earnings and profits without regard to the \$75 long-term capital gain and \$150 long-term capital loss for the post-October period of 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) the \$75 long-term capital gain and \$150 long-term capital loss for the post-October period of 1988 as if those deferred gains and losses arose on January 1, 1989. Thus, X will include

\$260 of capital gain in its earnings and profits for 1988 and \$55 of capital gain in its earnings and profits for 1989.

Example (4). Same facts as example (2), except that X elects to defer only \$50 of the post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) **Capital gain dividends.** Same results as in example (2).

(ii) **Taxable income.** X must compute its taxable income for 1988 without regard to the \$75 long-term capital gain and \$125 of the \$150 long-term capital loss for the post-October period of 1988 because it made an election to defer \$50 of the \$75 post-October capital loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net capital gain of \$75 and a net short-term capital gain of \$160. X must include the \$75 long-term capital gain and \$125 of the \$150 long-term capital loss for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X's taxable income for 1989 will include a net capital gain of \$10 and a net short-term capital gain of \$70.

(iii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the \$75 long-term capital gain and the \$150 long-term capital loss for the post-October period of 1988. X must include \$25 of the \$150 long-term capital loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) and \$75 long-term capital gain and \$125 of the \$150 long-term capital loss for the post-October period of 1988 as if those deferred gains and losses arose on January 1, 1989. Thus, X includes \$260 of capital gain in its earnings and profits for 1988, includes \$235 in its accumulated earnings and profits for 1988, and includes \$80 of capital gain in its earnings and profits for 1989.

Example (5). X has the following capital gains and losses for sales or exchanges made during the periods indicated:

	Long-term	Short-term
01/01 to 10/31/88	115 (15)	80 (20)
	100	60
11/01 to 12/31/88	150 (75)	50 (150)
	75	(100)
01/01 to 10/31/89	30 (5)	40 (20)
	25	20
11/01 to 12/31/89	35 (0)	100 (50)
	35	50

X has a post-October capital loss of \$25 for its 1988 taxable year due to a net capital loss for the post-October period of 1988. X does

not make an election under paragraph (f)(1) of this section.

(i) **Capital gain dividends.** X may designate up to \$100 as a capital gain dividend for 1988 because X must disregard the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 in computing its net capital gain for this purpose. In computing its net capital gain for 1989 for purposes of determining the amount it may designate as a capital gain dividend for 1989, X must take into account the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X may designate up to \$105 as a capital gain dividend for 1989.

(ii) **Taxable income.** X must include the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 in its taxable income for 1988 because it did not make an election under paragraph (f)(1) of this section for 1988. Accordingly, X's taxable income for 1988 will include a net capital gain of \$135 (consisting of a net long-term capital gain of \$175 and a net short-term capital loss of \$40). X's taxable income for 1989 will include a net capital gain of \$60 and a net short-term capital gain of \$70.

(iii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988. X must, however, include the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. Thus, X includes \$160 of capital gain in its earnings and profits for 1988, includes \$135 in its accumulated earnings and profits for 1988, and includes \$130 of capital gain in its earnings and profits for 1989.

Example (6). Same facts as example (5), except that X elects to defer the entire \$25 post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) **Capital gain dividends.** Same result as in example (5).

(ii) **Taxable income.** X must compute its taxable income for 1988 without regard to the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 because it made an election to defer the entire \$25 post-October capital loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net capital gain of \$100 and a net short-term capital gain of \$60. X must include the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term

capital gains and losses for 1989.

Accordingly, X's taxable income for 1989 will include a net capital gain of \$105 (consisting of a net long-term capital gain of \$135 and a net short-term capital loss of \$30).

(iii) **Earnings and profits.** For 1988, X must determine both its earnings and profits and its accumulated earnings and profits without regard to the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988 as if those deferred gains and losses arose on January 1, 1989. Thus, X will include \$160 of capital gain in its earnings and profits for 1988 and \$105 of capital gain in its earnings and profits for 1989.

Example (7). Same facts as example (5), except that X elects to defer only \$20 of the post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) **Capital gain dividends.** Same result as in example (5).

(ii) **Taxable income.** X must compute its taxable income for 1988 by including \$5 of the \$150 short-term capital loss for the post-October period of 1988, but without regard to the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and \$145 of the \$150 short-term capital loss for the post-October period of 1988 because it made an election to defer \$20 of the \$25 post-October capital loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net capital gain of \$100 and a net short-term capital gain of \$55. X must include the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and \$145 of the \$150 short-term capital loss for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X's taxable income for 1989 will include a net capital gain of \$110 (consisting of a long-term capital gain of \$135 and a net short-term capital loss of \$25).

(iii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and the \$150 short-term capital loss for the post-October period of 1988. In determining its accumulated earnings and profits for 1988, X must include \$5 of the \$150 short-term capital loss for the post-October period of 1988. In determining its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) the \$150 long-term capital gain, the \$75 long-term capital loss, the \$50 short-term capital gain, and \$145 of the \$150 short-term capital loss for the post-October period of 1988 as if those deferred gains and losses arose on

January 1, 1989. Thus, X includes \$160 of capital gain in its earnings and profits for 1988, includes \$155 in its accumulated earnings and profits for 1988, and includes \$110 of capital gain in its earnings and profits for 1989.

Example (8). X has the following capital gains and losses from sales or exchanges made during the periods indicated:

	Long-term	Short-term
01/01 to 10/31/88	115 (15)	80 (20)
	100	60
11/01 to 12/31/88	15 (75)	25 (10)
	(60)	15
01/01 to 10/31/89	80 (5)	50 (100)
	75	(50)
11/01 to 12/31/89	85 (0)	40 (20)
	85	20

X has a post-October capital loss of \$45 for its 1988 taxable year due to a net capital loss for the post-October period of 1988. X does not make an election under paragraph (f)(1) of this section.

(i) **Capital gain dividends.** X may designate up to \$100 as a capital gain dividend for 1988 because X must disregard the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 in computing its net capital gain for this purpose. In computing its net capital gain for 1989 for purposes of determining the amount it may designate as a capital gain dividend for 1989, X must take into account the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X may designate up to \$85 as a capital gain dividend for 1989.

(ii) **Taxable income.** X must include the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 in its taxable income for 1988 because it did not make an election under paragraph (f)(1) of this section for 1988. Accordingly, X's taxable income for 1988 will include a net capital gain of \$40 and a net short-term capital gain of \$75. X's taxable income for 1989 will include a net capital gain of \$130 for 1989 (consisting of a net long-term capital gain of \$160 and a net short-term capital loss of \$30).

(iii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988. X must, however, include the \$15 long-term capital gain, the \$75 long-term capital loss,

the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. Thus, X includes \$160 of capital gain in its earnings and profits for 1988, includes \$115 in its accumulated earnings and profits for 1988, and includes \$130 of capital gain in its earnings and profits for 1989.

Example (9). Same facts as example (8), except that X elects to defer the entire \$45 post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) **Capital gain dividends.** Same result as in example (8).

(ii) **Taxable income.** X must compute its taxable income for 1988 without regard to the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 because it made an election to defer the entire \$45 post-October capital loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net capital gain of \$100 and a net short-term capital gain of \$60. X must include the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term capital gains and losses for 1989.

Accordingly, X's taxable income for 1989 will include a net capital gain of \$85 (consisting of a net long-term capital gain of \$100 and a net short-term capital loss of \$15).

(iii) **Earnings and profits.** For 1988, X must determine both its earnings and profits and its accumulated earnings and profits without regard to the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988 as if those deferred gains and losses arose on January 1, 1989. Thus, X will include \$160 of capital gain in its earnings and profits for 1988 and \$85 of capital gain in its earnings and profits for 1989.

Example (10). Same facts as example (8), except that X elects to defer only \$30 of the post-October capital loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) **Capital gain dividends.** Same result as in example (8).

(ii) **Taxable income.** X must compute its taxable income for 1988 by including \$5 of the \$75 long-term capital loss and the \$10 short-term capital loss for the post-October period of 1988, but without regard to the \$15 long-term capital gain, \$70 of the \$75 long-term capital loss, and the \$25 short-term capital gain for the post-October period of 1988 because it made an election to defer \$30 of the \$45 post-October capital loss for 1988 under paragraph (f)(1) of this section.

Accordingly, X's taxable income for 1988 will include a net capital gain of \$95 and a net short-term capital gain of \$50. X must include the \$15 long-term capital gain, \$70 of the \$75 long-term capital loss, and the \$25 short-term capital gain for the post-October period of 1988 in its taxable income for 1989 in addition to the long-term and short-term capital gains and losses for 1989. Accordingly, X's taxable income for 1989 will include a net capital gain of \$100 (consisting of a net long-term capital gain of \$105 and a net short-term capital loss of \$5).

(iii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the \$15 long-term capital gain, the \$75 long-term capital loss, the \$25 short-term capital gain, and the \$10 short-term capital loss for the post-October period of 1988. In determining its accumulated earnings and profits for 1988, X must include \$5 of the \$75 long-term capital loss and the \$10 short-term capital loss for the post-October period of 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the long-term and short-term capital gains and losses for 1989) the \$15 long-term capital gain, \$70 of the \$75 long-term capital loss, and the \$25 short-term capital gain for the post-October period of 1988 as if those deferred gains and losses arose on January 1, 1989. Thus, X includes \$160 of capital gain in its earnings and profits for 1988, includes \$145 in its accumulated earnings and profits for 1989, and includes \$100 of capital gain in its earnings and profits for 1989 (consisting of a net long-term capital gain of \$105 and a net short-term capital loss of \$5).

Example (11). X has the following foreign currency gains and losses attributable to transactions during the periods indicated:

01/01 to 10/31/88	200
11/01 to 12/31/88	(100)
01/01 to 10/31/89	110
11/01 to 12/31/89	40

X has a \$100 post-October currency loss for its 1988 taxable year due to a net foreign currency loss for the post-October period of 1988. X does not make an election under paragraph (f)(1) of this section.

(i) **Taxable income.** X must compute its taxable income for 1988 by including the \$100 foreign currency loss for the post-October period of 1988 because it did not make an election under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net foreign currency gain of \$100. X's taxable income for 1989 will include a net foreign currency gain of \$150.

(ii) **Earnings and profits.** X must determine its earnings and profits for 1988 without regard to the foreign currency loss for the post-October period of 1988. X must, however, include the \$100 foreign currency loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. Thus, X includes \$200 of foreign currency gain in its earnings and profits for 1988, includes \$100 in its accumulated earnings and profits for 1988, and includes \$150 of foreign currency gain in its earnings and profits for 1989.

Example (12). Same facts as example (11), except that X elects to defer the entire \$100

post-October currency loss for 1988 under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) *Taxable income.* X must compute its taxable income for 1988 without regard to the \$100 foreign currency loss for the post-October period of 1988 because it made an election to defer the entire \$100 post-October currency loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net foreign currency gain of \$200. X's taxable income for 1989 will include a net foreign currency gain of \$50 because X must compute its taxable income for 1989 by including the \$100 foreign currency gain for the post-October period of 1988 in addition to the foreign currency gains and losses for 1989.

(ii) *Earnings and profits.* For 1988, X must determine both its earnings and profits and its accumulated earnings and profits without regard to the \$100 foreign currency loss for the post-October period of 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the foreign currency gains and losses for 1989) the \$100 foreign currency loss for the post-October period 1988 as if that deferred loss arose on January 1, 1989. Thus, X will include \$200 of foreign currency gain in its earnings and profits for 1988 and \$50 of foreign currency gain in its earnings and profits for 1989.

Example (13). Same facts as example (11), except that X elects to defer only \$75 of the post-October currency loss under paragraph (f)(1) of this section for purposes of determining its taxable income for 1988.

(i) *Taxable income.* X must compute its taxable income for 1988 by including \$25 of the \$100 foreign currency loss for the post-October period of 1988, but without regard to \$75 of the \$100 foreign currency loss for the post-October period of 1988 because it made an election to defer \$75 of the \$100 post-October currency loss for 1988 under paragraph (f)(1) of this section. Accordingly, X's taxable income for 1988 will include a net foreign currency gain of \$175. X's taxable income will include a net foreign currency gain of \$75 for 1989 because X must compute its taxable income for 1989 by including \$75 of the \$100 foreign currency loss for the post-October period of 1988 in addition to the foreign currency gains and losses for 1989.

(ii) *Earnings and profits.* X must determine its earnings and profits for 1988 without regard to the \$100 foreign currency loss for the post-October period of 1988. X must, however, include \$25 of the \$100 foreign currency loss for the post-October period of 1988 in determining its accumulated earnings and profits for 1988. In determining both its earnings and profits and its accumulated earnings and profits for 1989, X must include (in addition to the foreign currency gains and losses for 1989) the \$75 of the \$100 foreign currency loss for the post-October period of 1988 as if that loss arose on January 1, 1989. Thus, X includes \$200 of foreign currency gain in its earnings and profits for 1988, includes \$175 in its accumulated earnings and profits for 1988, and includes \$75 of foreign currency gain in its earnings and profits for 1989.

(i) *Procedure for making election—(1) In general.* Except as provided in paragraph (i)(2) of this section, a regulated investment company may make an election under paragraph (f)(1) of this section for a taxable year to which this section applies by completing its income tax return (including any necessary schedules) for that taxable year in accordance with the instructions for the form that are applicable to the election.

(2) *When applicable instructions not available.* If the instructions for the income tax returns of regulated investment companies for a taxable year to which this section applies do not reflect the provisions of this section, a regulated investment company may make an election under paragraph (f)(1) of this section for that year by entering the appropriate amounts on its income tax return (including any necessary schedules) for that year, and by attaching a written statement to the return that states—

(i) The taxable year for which the election under this section is made;

(ii) The fact that the regulated investment company elects to defer all or a part of its post-October capital loss or post-October currency loss for that taxable year for purposes of computing its taxable income under the terms of this section;

(iii) The amount of the post-October capital loss or post-October currency loss that the regulated investment company elects to defer for that taxable year; and

(iv) The name, address, and employer identification number of the regulated investment company.

(j) *Transition rules—(1) In general.* For a taxable year ending before March 2, 1990 in which a regulated investment company incurred a post-October capital loss or post-October currency loss, the company may use any method that is consistently applied and in accordance with reasonable business practice to determine the amounts taken into account in that taxable year for purposes of paragraphs (e)(2), (f)(3), and (g) of this section and to determine the amount taken into account in the succeeding year for purposes of paragraphs (e)(3), (f)(4), and (g) of this section. For example, for purposes of paragraph (e), a taxpayer may use a method that treats as incurred in a taxable year all capital gains from sales or exchanges after October 31 of that year and an amount of capital loss for such period equal to the amount of such gains and that treats the remaining amount of capital loss for such period as arising on the first day of the succeeding year.

Similarly, for purposes of paragraph (e)(3), a taxpayer may use a method that treats as arising on the first day of the succeeding year only the excess of the capital losses from sales or exchanges after October 31 over the capital gains for such period (that is, the net capital loss or net long-term capital loss for such period).

(2) *Retroactive election—(i) In general.* A regulated investment company may make an election under paragraph (f)(1) for a taxable year with respect to which it has filed an income tax return on or before May 1, 1990 (a "retroactive election") by filing an amended return (including any necessary schedules) for that taxable year reflecting the appropriate amounts and by attaching a written statement to the return that complies with the requirements of paragraph (i)(2) of this section.

(ii) *Deadline for making election.* A retroactive election may be made no later than December 31, 1990.

(3) *Amended return required for succeeding year in certain circumstances—(i) In general.* If, at the time a regulated investment company makes a retroactive election under this section, it has already filed an income tax return for the succeeding year, the company must file an amended return for such succeeding year reflecting the appropriate amounts.

(ii) *Time for filing amended return.* An amended return required under paragraph (j)(3)(i) of this section must be filed together with the amended return described in paragraph (j)(2)(i).

(4) *Retroactive dividend.* A regulated investment company that makes a retroactive election under this section for a taxable year may pay a dividend (a "retroactive dividend") with respect to that taxable year.

(5) *Deduction for dividends paid—(i) In general.* Subject to the rules of sections 561 and 562, a regulated investment company shall include the amount of any retroactive dividend paid under paragraph (j)(4) of this section in computing its deduction for dividends paid for the year to which the retroactive dividend relates.

(ii) *Declaration and payment date.* A retroactive dividend must be declared with respect to a taxable year on or before the date a retroactive election is made for that year under this section, and must be paid (or treated as paid under section 852(b)(7)) on or before December 31, 1990. No deduction for dividends paid shall be allowed under paragraph (j)(5)(i) of this section for any amount not paid (or treated as paid) on or before December 31, 1990.

(iii) *Limitation on ordinary dividends.* The amount of retroactive dividends (other than retroactive dividends qualifying as capital gain dividends) paid for a taxable year with respect to which a retroactive election is made under this section shall not exceed the increase, if any, in the investment company taxable income of the regulated investment company (determined without regard to the deduction for dividends paid (as defined in section 561)) that is attributable solely to the regulated investment company having made such election.

(iv) *Limitation on capital gain dividends.* The amount of retroactive dividends qualifying as capital gain dividends paid for a taxable year with respect to which a retroactive election was made under this section shall not exceed the increase, if any, in the amount of the excess described in section 852(b)(3)(A) (relating to the excess of the net capital gain over the deduction for capital gain dividends paid) that is attributable solely to the regulated investment company having made such election.

(v) *Effect on other years.* A retroactive dividend shall not be includible in computing the deduction for dividends paid for—

(A) The taxable year in which such distribution is actually paid (or treated as paid under section 852(b)(7)); or

(B) Under section 855(a), the taxable year preceding the taxable year with respect to which a retroactive election was made.

(vi) *Example.* The provisions of this paragraph (j)(5) may be illustrated by the following example:

Example. X is a regulated investment company that computes its income on a calendar year basis. No election is in effect under section 4982(e)(4). X has the following income for 1988:

Foreign Currency Gains and Losses:		Gains and losses	
		Short-term	Long-term
Jan. 1 to Oct. 31	100		
Nov. 1 to Dec. 31	(75)		
Capital Gains and Losses:			
Jan. to Oct. 31	100	100	
Nov. 1 to Dec. 31	50		(100)

(i) X had investment company taxable income of \$175 and no net capital gain for 1988 for taxable income purposes. X distributed \$175 of investment company taxable income as an ordinary dividend for 1988.

(ii) If X makes a retroactive election under this section to defer the entire \$75 post-October currency loss and the entire \$50

post-October capital loss for the post-October period of its 1988 taxable year for purposes of computing its taxable income, that deferral increases X's investment company taxable income for 1988 by \$25 (due to an increase in foreign currency gain of \$75 and a decrease in short-term capital gain of \$50) to \$200 and increases the excess described in section 852(b)(3)(A) for 1988 by \$100 from \$0 to \$100. The amount that X may distribute as a retroactive dividend is limited to \$25, and the amount that X may distribute as a retroactive capital gain dividend is limited to \$100.

(k) *Effective date.* The provisions of this section shall apply to taxable years ending after October 31, 1987.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 3. The authority for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 4. Section 602.101(c) is amended by inserting in the appropriate place in the table:

"1.852-11T * * * 1545-1094".

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is impracticable to issue this Treasury decision with notice and public procedure under section (b) of section 553 of title 5 the United States Code or subject to the effective date limitation of subsection (d) of that section.

Dated: January 18, 1990.

Charles H. Brennan,

Acting Commissioner of Internal Revenue.

Kenneth W. Gideon,

Assistant Secretary of the Treasury.

[FR Doc. 90-2220 Filed 1-30-90; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Ohio Regulatory Program; Crop Yields

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with certain exceptions, of Program Amendment Number 29R to the Ohio regulatory program (hereinafter referred to as the Ohio program) approved under the Surface Mining

Control and Reclamation Act of 1977 (SMCRA). The amendment consists of several revisions to the State rules concerning the use of crop yield data in bond release; success standards for tree plantings; approval by other State agencies of tree, shrub, and herbaceous species selection and stocking levels; and the definition of "countable tree." The amendment is intended to incorporate additional flexibility afforded by recent revisions to the corresponding Federal rules, revise the Ohio program to be consistent with the corresponding Federal rules, and to clarify the wording of the affected State rules.

EFFECTIVE DATE: January 31, 1990.

FOR FURTHER INFORMATION CONTACT:

Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43232; Telephone: (614) 866-0578.

SUPPLEMENTARY INFORMATION:

- I. Background on the Ohio Program
- II. Submission of Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval, can be found in the August 10, 1982, *Federal Register* (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified in 30 CFR 935.11, 935.12, 935.15 and 935.16.

II. Submission of Amendment

By letter dated May 6, 1987 (Administrative Record No. OH-937), the Ohio Department of Natural Resources, Division of Reclamation (Ohio), submitted proposed Amendment No. 29 to the Ohio program at Ohio Administrative Code (OAC) section 1501:13-9-15. The proposed revisions concerned revegetation standards initiated by Ohio. OSM announced receipt of the proposed amendment in the July 7, 1987, *Federal Register* (52 FR 25386), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment.

On July 27, 1987 (52 FR 28012), OSM announced a proposed rule to revise the

Federal regulations dealing with the same revegetation standards as were proposed for revision in Ohio's amendment of May 6, 1987. To avoid the need for Ohio to amend its revegetation regulations a second time following approval of the revised Federal rules, OSM and Ohio agreed to defer action on the proposed Ohio amendment until the corresponding Federal rules had been finalized (Administrative Record Nos. OH-0980 and OH-0986). The final Federal rules were adopted by OSM on September 7, 1988 (53 FR 34636).

By letter dated January 26, 1989 (Administrative Record No. OH-1135), Ohio submitted revised proposed Amendment No. 29R to the Ohio program at Ohio Administrative Code (OAC) Section 1501:13-9-15. The revisions, along with accompanying administrative record documents, was intended to make the Ohio program consistent with the Federal revegetation rules adopted on September 7, 1988.

Previous administrative record documents submitted with Ohio Amendment No. 28 also pertain to the changes proposed by Ohio in Amendment No. 29R and are referred to in the Director's findings and decision on Amendment No. 29R. These documents include an Ohio policy statement of July 14, 1988, submitted by letter dated July 6, 1988 (Administrative Record No. OH-1070), and supporting information dated April 17, 1987 (Administrative Record No. OH-0931), and November 2, 1987 (Administrative Record No. OH-0991). These previous administrative record documents are considered part of Ohio's submission of proposed Amendment No. 29R.

OSM announced receipt of the proposed amendment in the March 1, 1989, *Federal Register* (54 FR 8562), and in the same notice opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment.

On December 13, 1989, Ohio submitted revisions to proposed Amendment No. 29R to correct citation errors at OAC 1501:13-9-15(I)(2)(b) and 1501:13-9-15(I)(3). These revisions are not significant and, therefore, OSM did not reopen the public comment period.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Ohio program at OAC 1501:13-9-15.

1. Definition of "Countable Trees"

OAC 1501:13-9-15(A)(1)(a). Ohio is revising its definition of "countable

tree" concerning the time period for which a tree or shrub must be in place in order to be considered a "countable tree." The revised definition is nearly identical to that portion of 30 CFR 816/817.116(b)(3)(ii), as revised on September 7, 1988 (53 FR 34643), which specifies that no tree or shrub in place for fewer than two growing seasons shall be counted in determining revegetation success.

The reader is referred to the approval of Ohio Program Amendment No. 28 published in the *Federal Register* on February 21, 1989 (54 FR 7406-7409) for additional discussion of Ohio's definition of "countable tree." In that notice, the Director approved a revision to the definition of "countable tree" which defined "countable tree" to mean a tree or shrub in place for two growing seasons, rather than five years as in the previous rule. In the administrative record accompanying the April 17, 1987 submission of Program Amendment No. 28 (Administrative Record No. OH-0931), Ohio states that it will interpret the phrase "two growing seasons" as meaning "two years" when determining whether a woody plant is countable under the revised definition. The proposed amendment, therefore, more accurately reflects Ohio's implementation of its revegetation success standards.

The Director finds that the State's revised definition of "countable tree" at OAC 1501:13-9-15(A)(1)(a) is no less effective than the corresponding requirements of 30 CFR 816/817.116(b)(3)(ii).

2. Consultation With and Approval by Other Agencies

(a) OAC 1501:13-9-15 (F), (G), and (H). Ohio is moving the existing versions of paragraphs (F)(9), (F)(10), and (F)(11), respectively, to these new paragraphs. Paragraph notations throughout OAC Section 1501:13-9-15 are being revised to reflect the relocation of these paragraphs. Ohio is also revising paragraphs (F) and (G) to require consultation with and approval by the Ohio Department of Natural Resources, Division of Forestry, of Ohio's determinations of appropriate species of trees and shrubs, appropriate stocking levels of trees and shrubs, and appropriate herbaceous species for areas where the postmining land use is to be recreation, shelter belts, non-commercial forest land, or commercial forest land. Ohio is also revising paragraph (H) to require consultation with and approval by the Ohio Department of Natural Resources, Division of Wildlife, of Ohio's determinations of appropriate species of

trees and shrubs, appropriate stocking levels of trees and shrubs, and appropriate herbaceous species for areas where the postmining land use is fish and wildlife habitat.

(b) OAC 1501:13-9-15(I)(8)(b). Ohio is revising this paragraph to reiterate that both consultation with and approval by the appropriate State agency must occur as part of Ohio's determination of tree and shrub species compatible with the postmining land use.

The revisions proposed by Ohio will make the affected rules nearly identical with 30 CFR 816/817.116(b)(3)(i), as revised on September 7, 1988 (53 FR 34643), which requires consultation with and approval of minimum stocking and planting arrangements by the State agencies responsible for the administration of forestry and wildlife programs.

Therefore, the Director finds that the State's relocation and revision of OAC 1501:13-9-15(F), (G), and (H) and the revision of OAC 1501:13-9-15(I)(8)(b) are no less effective than the corresponding requirements of 30 CFR 816/817.116(b)(3)(i).

3. Effect of Non-Augmentative Agronomic Practices on the Period of Extended Responsibility for Revegetation Success

(a) OAC 1501:13-9-15(I)(2)(c)(i). Ohio proposes to amend its rules to allow seeding, fertilizing, irrigating and other locally accepted practices on cropland or pastureland without restarting the Phase III bond liability period. The Federal rules at 30 CFR 816.116(c)(1) require that the period of extended responsibility for successful revegetation shall begin after the last year of augmented seeding, fertilizing, irrigation, or other work, excluding husbandry practices that are approved by the regulatory authority in accordance with 30 CFR 816.116(c)(4). The proposed practices will be considered non-augmentative by Ohio when the agronomic practice and the rate of application is an accepted local practice for comparable unmined land that can be expected to continue following bond release. An amendment with similar language was proposed by Ohio as part of Program Amendment No. 28, and the final rule notice for Program Amendment No. 28 was published in the *Federal Register* on February 21, 1989 (54 FR 7406-7409).

As a consequence of OSM's review of Program Amendment No. 28, the Director made a finding that the portion of the rule concerning non-augmentative seeding, fertilizing and irrigation, which allows the use of "other locally accepted

practices" is inconsistent with 30 CFR 816/817.116(c)(4), which requires that each specific practice be approved through the State program amendment process. In addition, the Director required that Ohio shall submit a proposed amendment to the rule concerning non-augmentative seeding, fertilizing and irrigation (OAC 1501:13-9-15(F)(12)(a) at the time) to remove the phrase "and other locally accepted practices" or otherwise propose to amend its program to clarify that all normal husbandry practices must be approved by OSM pursuant to 30 CFR 732.17.

The reader is referred to the Federal Register notice of February 21, 1989, Finding 2(a), (b), and (c) for a complete discussion of Ohio's proposed rules concerning non-augmentative seeding, fertilizing and irrigation. Since Ohio's currently proposed language concerning non-augmentative seeding, fertilizing and irrigation is nearly identical to the language proposed in Program Amendment No. 28, the Director's findings published on February 21, 1989 still apply.

Therefore, the Director finds that the proposed amendment at OAC 1501:13-9-15(I)(2)(c)(i) is no less effective than the Federal rules except that the portion of the Ohio rule allowing the use of unspecified "other locally accepted practices" is inconsistent with 30 CFR 816/817.116(c)(4), which requires that each specific practice be approved through the State program amendment process.

(b) OAC 1051:13-9-15(I)(2)(c)(ii). Ohio proposes to add provisions to designate the repair of rills and gullies on cropland and areas planted to woody vegetation as a non-augmentative cultural practice. An amendment with similar language was proposed by Ohio as part of Program Amendment No. 28, and the final rule notice for Program Amendment No. 28 was published in the Federal Register on February 21, 1989 (54 FR 7406-7409). As a consequence of OSM's review of Program Amendment No. 28, the Director required that Ohio further amend the provision concerning the non-augmentative repair of rills and gullies (OAC 1501:13-9-15(F)(12)(b)) to clarify that its applicability will be limited to minor erosional features on lands on which proper erosion control practices are in use and to non-recurrent rills and gullies affecting only small areas.

The reader is referred to the Federal Register notice of February 21, 1989, Finding 2(d) for a complete discussion of Ohio's proposed rules concerning non-augmentative repair of rills and gullies. Since Ohio's currently proposed

language concerning non-augmentative repair of rills and gullies is nearly identical to the language proposed in Program Amendment No. 28, the Director's findings published on February 21, 1989 still apply. Therefore, the Director is continuing to require that Ohio further amend the provision concerning the repair of rills and gullies to clarify that its applicability will be limited to minor erosional features on lands on which proper erosion control practices are in use and to non-recurrent rills and gullies affecting only small areas.

(c) OAC 1501:13-9-15(I)(2)(c)(iii). Ohio proposes to allow the replanting of trees as a reinforcement measure in areas where the postmining land use requires woody plants as the primary vegetation. This amendment, coupled with the proposed provisions at OAC 1501:13-9-15 (A)(1)(a) and (I)(8)(f)(i), will require that no tree or shrub in place less than two years may be considered a countable tree and that at least 80 percent of all countable trees be in place at least three years. This restriction on the extent to which reinforcement planting may be considered non-augmentative is substantively similar to the corresponding Federal rules at 30 CFR 816/817.116(c)(4). An amendment with similar language was proposed by Ohio as part of Program Amendment No. 28, and the final rule notice for Program Amendment No. 28 was published in the Federal Register on February 21, 1989 (54 FR 7406). As a consequence of OSM's review of Program Amendment No. 28, the Director determined that the proposed provision was no less effective than the Federal rules at 30 CFR 816/817.116(c)(4) as revised on September 7, 1988 (53 FR 34643). Therefore, the Director finds that the proposed rule is no less effective than the corresponding Federal rule at 30 CFR 816/817.116(c)(4).

4. Phase III Revegetation Release

OAC 1501:13-9-15(I)(4)(c). Ohio is revising this paragraph to specify that revegetation shall be determined to be successful for Phase III bond release for row and hay crops when the five-year period of extended responsibility has expired and the yield data of crop harvest on the mined area for any two years of the period of extended responsibility, except the first year, equals or exceeds the average county yield for comparable crops.

The revisions proposed by Ohio will make the affected rule nearly identical with 30 CFR 816/817.116(c)(2), as revised on September 7, 1988 (53 FR 34643), which requires that crop yields shall equal or exceed the approved success

standard during the growing seasons of any two years of the responsibility period, except the first year.

Therefore, the Director finds that the State's revision of OAC 1501:13-9-15(I)(4)(c) is no less effective than the corresponding requirements of 30 CFR 816/817.116(c)(2).

5. Revegetation Success Determination for Areas With Woody Plants as the Primary Vegetation

(a) OAC 1501:13-9-15(I)(8). Ohio is revising this paragraph to delete the phrase "a cover of" from the requirement to establish trees and shrubs after mining where the approved postmining land use requires woody plants as the primary vegetation.

(b) OAC 1501:13-9-15(I)(8)(b). Ohio is revising this paragraph to change the phrase "well-distributed acceptable trees" to "properly distributed acceptable trees."

The minor wording revisions in these sections are strictly editorial and nonsubstantive in nature.

Therefore, the Director finds that these changes are no less effective than their Federal counterparts in 30 CFR 816/817.116.

6. Phase III bond release requirements for countable trees

OAC 1501:13-9-15(I)(8)(f)(i). Ohio is revising this paragraph to increase the minimum number of countable trees required for Phase III bond release from four hundred per acre to four hundred and fifty per acre, and to add the requirement that eighty percent of the trees must have been in place for at least three years. An amendment with similar language was proposed by Ohio as part of Program Amendment No. 28, and the final rule notice approving these provisions was published in the Federal Register on February 21, 1989 (54 FR 7406-7409). Proposed OAC 1501:13-9-15(I)(8)(f)(i) also states that for areas where the postmining land use is fish and wildlife habitat, the areas must have a minimum of two hundred fifty countable trees per acre, of which eighty percent must have been in place for three years.

The revised figure of 450 minimum countable trees per acre is 75 percent of the stocking required for Phase II bond release and is in keeping with the 75 percent success standard for forest plantations established under the regulations implementing the Forest Tax Law of Ohio (sections 5713.22 through 5713.26 of the Ohio Revised Code). The corresponding Federal rules at 30 CFR 800.40 and 816/817.116 lack a counterpart provision; however, the

Director finds that this modest increase in the required stocking represents good silvicultural practice and is not inconsistent with the requirements of SMCRA and the Federal regulations.

The rule also requires that, at the time of Phase III bond release, at least 80 percent of the countable trees have been in place at least three years. As discussed in Finding 1, Ohio has adequately documented that, in a plantation, trees which survive more than two years and are in a healthy state can be considered established. The corresponding Federal rule at 30 CFR 816/817.116(b)(3)(ii), as revised on September 7, 1988, 53 FR 34643, requires that, at the time of final bond release, at least 80 percent of the trees and shrubs used to determine success have been in place at least 60 percent of the applicable minimum period of responsibility. In Ohio, the applicable minimum period is five years. Since the revision proposed by Ohio would require that 80 percent of the countable trees be in place at least three years (60 percent of five years), the revised rule is no less effective than its Federal counterparts.

Ohio is also revising this rule to require that fish and wildlife habitat areas must have a minimum of two hundred fifty countable trees per acre, of which eighty percent must have been in place for three years. The corresponding Federal rule at 30 CFR 816/817.116(b)(3)(i), (ii), and (iii), as revised on September 7, 1988, 53 FR 34643, allows minimum stocking and planting arrangements for fish and wildlife habitat to be established by the regulatory authority. Documents provided by Ohio (Administrative Record OH-1135) indicate that Ohio has consulted with and obtained the approval of the Ohio Department of Natural Resources, Divisions of Forestry and Wildlife in the development of these success standards as required by 30 CFR 816/817.116(b)(3)(i). The Director therefore finds that the revised rule is no less effective than its Federal counterpart.

7. Schedule for Filing of Planting Reports

OAC 1501:13-9-15(I)(9). Ohio is revising this paragraph to specify that permittees shall file planting reports upon completion of planting rather than prior to, or simultaneously with, an application for Phase II bond release of the planted area.

The corresponding Federal rules at 30 CFR 816/817.116 lack a counterpart provision. The Director finds that this revision is not inconsistent with the

requirements of SMCRA and the Federal regulations.

IV. Summary and Disposition of Comments

Public Comments

The public comment period announced in the March 1, 1989, *Federal Register* (54 FR 8562) ended March 31, 1989. No public comments were received. The scheduled public hearing was not held as no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Ohio program. The U.S. Environmental Protection Agency responded that it had no comments on the proposed amendment. No other comments were received.

V. Director's Decision

Based on the findings discussed above, the Director is approving Ohio Program Amendment No. 29R as submitted on January 26, 1989 and amended on December 13, 1989, with the exception of the provision discussed in Finding 3(a) and 3(b), as interpreted by the letters and policy statements submitted on November 2, 1987, and July 6, 1988.

As discussed in Finding 3(b), the Director is also requiring that Ohio further amend its program to clarify the circumstances under which the repair of rills and gullies may be considered a non-augmentative practice. As provided by 30 CFR 732.17(a) and (g), any provision not approved by the Director may not be implemented as part of the Ohio program. The Director is amending 30 CFR part 935 to implement this decision.

This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to the State program are not enforceable

until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. In his oversight of the Ohio program, the Director will recognize only the statutes, regulations and other materials approved by him, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Ohio of only such provisions.

VI. Procedural Determinations

National Environmental Policy Act

The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

Executive Order 12291 and the Regulatory Flexibility Act

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a regulatory impact analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal regulations will be met by the State.

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 935

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: January 22, 1990.

Carl C. Close,

Assistant Director, Eastern Field Operations.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 935—OHIO

1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 935.15, a new paragraph (II) is added to read as follows:

§ 935.15 Approval of regulatory program amendments.

(II) With the exception noted herein, the following amendment, as submitted to OSM on January 26, 1989 and amended on December 13, 1989, is approved effective [January 31, 1990]: Revisions to the following paragraphs of Rule 13-9-15 of chapter 1501 of the Ohio Administrative Code: (A)(1)(a), (F), (G), (H), (I)(2)(c), (I)(4)(c), (I)(8), (I)(8)(b), (I)(8)(i), and (I)(9) except for the phrase "and other locally accepted practices" in paragraph (I)(2)(c)(i) and (I)(2)(c)(ii) to the extent that rills and gullies will not be universally considered non-augmentative.

3. In § 935.16 paragraphs (c) and (d) are revised to read as follows:

§ 935.16 Required regulatory program amendments.

(c) By June 1, 1990, Ohio shall submit a proposed amendment to OAC 1501:13-9-15(I)(2)(c)(i) to remove the phrase "and other locally accepted practices" or otherwise propose to amend its program to clarify that all normal husbandry practices must be approved by OSM pursuant to 30 CFR 732.17.

(d) By June 1, 1990, Ohio shall submit a proposed amendment to OAC 1501:13-9-15(I)(2)(c)(ii) or otherwise propose to amend its program to clarify that the repair of rills and gullies will not be universally considered non-augmentative, and that this determination will be made based on the extent of repairs needed and the cause of the erosion.

[FR Doc. 90-2165 Filed 1-30-90; 8:45 am]
BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 154

Department of Defense Personnel Security Program Regulation

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: The provision of § 154.16(c) regarding citizenship and residency requirements for naturalized U.S. citizens from "designated" countries to be eligible for a DoD security clearance,

were rescinded February 12, 1988, pursuant to a preliminary injunction in the U.S. District Court for the District of Columbia.

EFFECTIVE DATE: January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Nelson, Office of the Deputy Under Secretary of Defense (Security Policy), Counterintelligence and Investigative Programs, Room 3C267, The Pentagon, Washington, DC 20301-2200, telephone (202) 697-3039.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 154

Classified information; Government employees; Investigations; Security measures.

Accordingly, 32 CFR part 154 is amended as follows:

PART 154—[AMENDED]

1. The authority citation for part 154 continues to read as follows:

Authority: E.O. 10450; E.O. 12365; E.O. 10865; E.O. 12333.

§ 154.16 [Amended]

2. Section 154.16 is amended by removing § 154.16(c) and redesignating paragraph (d) through (i) as (c) through (h).

Dated: January 25, 1990.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 90-2130 Filed 1-30-90; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611 and 672

[Docket No. 91050-0019]

Foreign Fishing; Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final notice of 1990 initial specifications of groundfish; sablefish assignments; proposed apportionment of reserves; assumed Pacific halibut bycatch and mortality rates; information pertaining to prohibited species catch limits for fully utilized species; inseason adjustment relevant to the pollock fishery; and request for comments.

SUMMARY: The Secretary of Commerce (Secretary) announces initial specifications of groundfish in the Gulf of Alaska for the 1990 fishing year and

certain other measures that are being implemented to manage the 1990 groundfish fisheries in the Gulf of Alaska. This action is necessary to inform the public of the Secretary's determinations. The measures are intended to carry out management objectives contained in the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP).

DATES: Effective: January 26, 1990; 10:37 a.m. Comments are invited on the proposed apportionments of reserves and on the inseason adjustment in the pollock fishery until February 12, 1990.

ADDRESSES: Comments should be sent to Steven Pennoyer, Director, Alaska Region, National Marine Fisheries Service, P.O. Box 021668, Juneau, AK 99802.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION:

Background

This notice announces for the 1990 fishing year: (1) Total allowable catches (TACs) for each category of groundfish in the Gulf of Alaska and apportionments thereof among domestic annual processing (DAP), joint venture processing (JVP), total allowable level of foreign fishing (TALFF), and reserves; (2) assignments of the sablefish TAC to authorized fishing gear users; (3) apportionments of reserves to DAP; (4) assumed bycatch rates and mortality rates pertinent to prohibited species catch (PSC) limits of Pacific halibut that are applicable to the DAP fishery; (5) zero PSC limits relevant to fully utilized species; and (6) an inseason adjustment in the Gulf of Alaska pollock fishery.

(1) Establishment of TACs and Apportionments Thereof Among DAP, JVP, TALFF, and Reserves

The process for determining TACs for groundfish species in the Gulf of Alaska is established by the FMP. This FMP was developed by the North Pacific Fishery Management Council (Council) under the Magnuson Act and is implemented by regulations appearing at 50 CFR 611.92 and part 672. The sum of the TACs for all species must fall within the combined optimum yield (OY) range established for these species of 116,000-800,000 metric tons (mt).

TACs are apportioned initially among DAP, JVP, TALFF, and reserves for each species under § 611.92 and 672.20(a)(2). DAP amounts are intended for harvest by U.S. fishermen for delivery and sale to U.S. processors. JVP amounts are intended for joint ventures in which U.S.

fishermen typically deliver their catches to foreign processors at sea. TALFF amounts are intended for harvest by foreign fishermen. The reserves for the Gulf of Alaska are 20 percent of the TAC for pollock, Pacific cod, flatfish species, and "other species". If necessary, these reserve amounts may be set aside for possible reapportionment to DAP and/or to JVP if the initial apportionments prove inadequate. Reserves which are not reapportioned to DPA or JVP may be reapportioned to TALFF. Other groundfish target species, including sablefish, "other rockfish", pelagic shelf rockfish, demersal shelf rockfish, and thornyhead rockfish are fully utilized by DAP and no reserves are established.

Under 36 72.20(c)(1), the preliminary specifications of DAP were published in the *Federal Register* (54 FR 40743, November 7, 1989). No JVP amounts were specified. Comments were requested to be submitted to the Regional Director through December 1, 1989. One letter of comments was received by the Regional Director. It is summarized and responded to in the "Comments Received" section.

The Council met during December 5-8, 1989 to review the best available scientific information concerning groundfish stocks, intended harvest plans for 1990, and estimates made by NMFS concerning the extent to which U.S. fishermen would harvest amounts of groundfish. This information was contained in the Stock Assessment and Fishery Evaluation (SAFE) report, which was prepared and presented by the Gulf of Alaska Groundfish Plan Team to the Council and to the Council's Scientific and Statistical Committee (SSC) and Advisory Panel (AP). Information contained in the SAFE report included results obtained from the 1984 and 1987 triennial trawl survey of groundfish conducted in the Gulf of Alaska and the 1986 and 1988 hydroacoustic survey of pollock in Shelikof Strait, which lies between Kodiak Island and the Alaska Peninsula. Both surveys were conducted by the NMFS Alaska Fisheries Science Center. The Council's SSC reviewed the available information and recommended to the Council acceptable biological catches (ABCs) discussed below and shown in table 1 contained at § 672.20. Acceptable biological catches are estimated by multiplying exploitable biomass times the exploitable rate chosen by the Council. The AP also considered information contained in the SAFE report and recommended TACs for each species.

Most of the information considered by the Council was summarized in the preliminary notice. Any new information and subsequent actions by the Council for each species and species

complex are summarized below:

A. Total Allowable Catches

Pollock—The condition of pollock is depressed. Data from the hydroacoustic surveys and the 1984 and 1987 bottom trawl surveys were analyzed, using the Stock Synthesis Model. The Plan Team adopted a modeling approach, which emphasizes information from the bottom trawl surveys as being superior to that obtained from the hydroacoustic surveys. Potential yield was calculated on the assumption that the 1987 year class is either average or poor in strength. The Plan Team determined that the most correct assumption is that the strength of the 1987 year class is poor, based on a preliminary examination of a fall 1989 bottom trawl survey. The Plan Team recommended that the combined ABC in the Western/Central Regulatory Area and the Shelikof District should be 70,000 mt, which is the average of three projections of potential yield—79,000, 68,000, and 62,000 mt. The SSC adopted the Plan Team's recommendation with 6,250 mt of the ABC to be apportioned to the Shelikof District.

No new information for the Eastern Regulatory Area is available to change the 1990 ABC of 3,400 mt. The AP recommended that TACs for the Western/Central Regulatory Area, Shelikof District, and Eastern Regulatory Area should be set equal to the SSC's recommendation for ABC, and that DAP should equal TAC. The Council adopted the SSC recommendations for ABC, and the AP recommendations for TAC and DAP, respectively.

Pacific cod—Although Pacific cod stocks appear to be decreasing in size, stocks are still healthy. The best estimate of exploitable biomass Gulf of Alaska-wide is 498,044 mt. Although this value is about 11 percent less than the 1989 estimate, the difference resulted from the different assumptions used in the Stock Reduction Analysis employed to determine biomass. The Plan Team recommended an ABC of 60,500 mt, which was derived by applying the F_{msy} exploitation rate to exploitable biomass. The SSC believed this value underestimates the F_{msy} fishing mortality rate. Lacking a better F_{msy} estimate, the SSC recommended an exploitation of 25 percent, which is the $F_{0.1}$ exploitation rate. This rate is less than the estimated rate of natural mortality and is believed to be less than F_{msy} . Using $F_{0.1}$, the SSC recommended an ABC of 120,000 mt. The AP adopted the SSC's recommendation but recommended that TAC should be 90,000 mt with DAP set equal to TAC. The Council recommended an ABC and TAC of 90,000 mt with TAC apportioned among the regulatory areas as follows:

Western—29,500 mt; Central—59,500 mt; and Eastern—1,000 mt.

Flatfish—Stocks of all flatfish species, including deepwater flatfish, shallow water flatfish, and arrowtooth flounder, are in good condition. The Plan Team recommended that respective ABCs should be set equal to 228,000 mt, 207,100 mt, and 343,300 mt, using an exploitation strategy that maximizes the yield per recruit for a given age in the fishery (F_{max}). However, the SSC believes that F_{max} is not appropriate, because it assumes that recruitment is completely independent of spawning stock and ignores the effects of fishing on spawning stock and subsequent recruitment. The SSC instead recommended a $F_{0.1}$ fishing mortality rate for all flatfish species, which results in the following ABCs for deepwater flatfish, shallow water flatfish, and arrowtooth flounder: 108,400 mt, 84,500 mt and 194,600 mt, respectively. In each case, the AP adopted the SSC's ABCs but reduced TACs substantially to reflect industry needs. The AP then recommended that DAP be set equal to TAC for each flatfish category. The Council adopted the SSC's recommendations for ABCs but set TACs equal to those recommended by the AP for deepwater flatfish, shallow water flatfish, and arrowtooth flounder. It then set each DAP equal to TAC with distributions among the regulatory areas as follows:

Deepwater flatfish—Western—3,650 mt; Central—15,300 mt; and Eastern—3,050 mt.

Shallow water flatfish—Western—3,570 mt; Central—6,180 mt; and Eastern—250 mt.

Arrowtooth flounder—Western—4,450 mt; Central—23,170 mt; and Eastern—4,380 mt.

Sablefish—Results of the 1989 Japan-U.S. cooperative longline survey and a domestic longline survey indicate the sablefish biomass may be declining. Using a pessimistic biomass estimate for sablefish, Gulf of Alaska-wide, the Plan Team recommended an ABC of 26,200 mt, which is a decrease from the 1989 level of 30,900 mt. This recommendation is conservative but compensates for lack of evidence of a strong 1984 year class that was expected to fully recruit to the fishery in 1990. The SSC concurred with the Plan Team's recommendation that the ABC is 26,200 mt. Because the 1989 TAC equaled 26,000 mt, the AP recommended that the 1990 TAC equal the 1989 TAC, or 26,000 mt. The Council adopted the SSC's and the AP's recommendations and set DAP equal to TAC, apportioned among the regulatory areas and districts as follows: Western—3,770 mt; Central—11,700 mt; West Yakutat—4,550 mt; and Southeast Outside/East Yakutat—5,980 mt.

Rockfish assemblages—The same three categories of rockfish in the genus *Sebastes* will be managed in 1990 as in 1989. These categories are "other rockfish", pelagic shelf rockfish, and demersal shelf rockfish. They are described as follows: "Other rockfish"—In the Western and Central Regulatory Areas and the Eastern Regulatory Area west of 137° W. longitude, "other rockfish" means the 18 species of slope rockfish and the 10 species of demersal shelf rockfish listed in the footnotes to Table 1 of this notice. TACs are established for these combined assemblages in these management areas. In the Southeast Outside District, "other rockfish" means the 18 species of slope rockfish only. A TAC is established for this assemblage of 18 species in the Southeast Outside District.

Pelagic shelf rockfish—In the Western, Central, and Eastern Regulatory Areas, pelagic shelf rockfish means the five rockfish species listed in the footnote to table 1 of this notice. A TAC is established for this assemblage in each of these regulatory areas.

Demersal shelf rockfish—In the Southeast Outside District, demersal shelf rockfish means the ten rockfish species listed in the footnote to table 1 of this notice. A TAC is established only in the Southeast Outside District.

The condition of, and Council action for, each of the rockfish assemblages that make up the three categories are as follows:

The condition of slope rockfish referred to as "other rockfish" in table 1, is good and stocks are believed to be increasing in abundance. Exploitable biomass is estimated to be about 702,200 mt. About 14 percent of this amount, or 99,700 mt, is composed of a subcategory called "deep slope" rockfish. The balance is composed of a subcategory called "shallow slope" rockfish. The Plan Team recommended a Gulf of Alaska-wide ABC of 17,700 mt, which is 50 percent of the sum of the individual species ABCs for this species complex. This conservative ABC affords some protection to two species in the complex, which are low in abundance. The SSC concurred with the Plan Team's recommendation. The AP recommended a TAC higher than the ABC for market reasons, and because the SSC's recommendation was conservative. The Council set TACs equal to the SSC's ABCs and set each DAP equal to TAC distributed among the regulatory areas as follows: Western—4,300 mt; Central—7,700 mt; and Eastern—5,700 mt.

For pelagic shelf rockfish, the Plan Team recommended a Gulf of Alaska-

wide ABC of 8,200 mt, which the SSC adopted. The AP recommended a TAC equal to ABC. The Council adopted the SSC's and the AP's recommendations and set DAP equal to TAC apportioned among the regulatory areas as follows: Western 1,400 mt; Central—5,800 mt; and Eastern—1,000 mt.

For demersal shelf rockfish, no biomass or yield estimates are available on which to base an ABC. This rockfish assemblage is the target of a hook-and-line fishery in the Southeast Outside District. Information from the Alaska Department of Fish and Game on this rockfish assemblage suggests that the population is declining. The Council adopted a TAC of 470 mt, based on a State of Alaska recommendation that no more than this amount should be harvested from the Southeast Outside District.

Thornyhead rockfish—The SSC adopted the Plan Team's recommendation that the ABC should be set equal to the 1989 amount of 3,800 mt. The Council adopted this number and recommended a Gulf of Alaska-wide TAC equal to ABC, and set DAP equal to TAC.

Other species—No recommendations were made by the Plan Team for this group. Under the FMP, the TAC for this species category is to be set at 5 percent of the sum of the TACs established for the other groundfish categories. Thus TAC is 14,179 mt.

The sum of the above TACs adopted by the Council is 297,749 mt, which falls within the OY range specified by the FMP. The Council, after adopting the TACs, then deliberated on the apportionment of the TACs for each species among DAP, JVP, TALFF, and reserve. The Council reviewed the results of the NMFS U.S. processor survey that was conducted prior to the Council's meeting. This survey queries the U.S. processing industry about its processing capacity and the extent to which that capacity will be used for groundfish species in 1990. This survey did not include sablefish and the rockfish species, which are known to be fully utilized as evidenced by prior years' harvests. The survey did include pollock, Pacific cod, and flatfish. When the Regional Director reviewed the survey results, he calculated the probability that those amounts would actually be processed, considering the amount of processing machinery that was available or which was planned for but not yet in place, both in shoreside processing facilities and on catcher/processor and mothership processor vessels.

In doing so, the Regional Director discounted some of the survey results as overly optimistic. The Regional Director

presented his analysis to the Council, which in turn considered its findings when making recommendations to the Secretary for initial DAP specifications. As a result of this process, TALFF and JVP are set at zero, because all species are expected to be fully utilized by U.S. fishermen in DAP fisheries. For pollock and Pacific cod, NMFS projections of DAP needs exceed TACs for these species. For flatfish, NMFS projections of DAP needs are less than TAC. The Council, however, received considerable information from the public that the flatfish fishery will expand substantially more than indicated by the NMFS survey needs, and that the DAP should equal TAC for each of the three flatfish categories. For sablefish and all the rockfish species, including thornyhead rockfish, all TACs are expected to be fully utilized by DAP, and no amount is available for JVP.

The Secretary has reviewed the Council's recommendations for TAC specifications and apportionments and hereby implements these specifications under § 672.20(c)(1).

B. Proposed Apportionment of Reserves to DAP

The FMP stipulates that 20 percent of each TAC for pollock, Pacific cod, flatfish species, and the "other species" category be set aside in a reserve for possible reapportionment at a later date. Because DAP is projected to need all reserves, the Secretary, at this time, under § 672.20(d)(1)(ii) and (d)(3) is proposing to reapportion reserves for each species category to DAP. By doing so, the Secretary is anticipating that the domestic industry will need all of the DAP amounts so specified. Specifications of DAP shown in table 1 of this notice reflect proposed DAP totals if the reserves are apportioned following a 15 day comment period. Under § 672.20(d)(5)(iv), comments should focus on whether, and the extent to which, vessels of the United States will harvest reserve or DAH amounts during the remainder of the year and whether, and the extent to which, U.S. harvested groundfish can or will be processed by U.S. fish processors or received at sea by foreign fishing vessels.

C. Assignments of the Sablefish TAC to Authorized Fishing Gear Users

Under § 672.24(b), sablefish TACs for each of the regulatory areas and districts are further assigned to hook-and-line and trawl gear. The Secretary publishes for the information of the public the following table that shows the assignments of sablefish TACs between the gear types:

SABLEFISH TOTAL ALLOWABLE CATCH (TAC) AND AMOUNTS OF TAC, IN METRIC TONS, ALLOCATED TO AUTHORIZED GEAR IN THE REGULATORY AREAS AND DISTRICTS OF THE GULF OF ALASKA

Area/District	TAC	Hook-and-line share	Trawl share
Western	3,770	3,020	750
Central	11,700	9,360	2,340
West Yakutat	4,550	4,320	230
Southeast Outside/ East Yakutat	5,980	5,680	300
Total	26,000	22,380	3,620

D. PSC Limits Relevant to Fully Utilized Species

Under § 672.20(b)(1), if the Secretary determines after consultation with the Council that the TAC for any species or species group will be fully utilized in the DAP fishery, he may specify the PSC limit applicable to the JVP fisheries for that species or species group. Any PSC limit specified shall be for bycatch only and cannot be retained. Under § 672.20(c)(iv), if the Regional Director determines that a PSC limit applicable to a directed JVP fishery has been or will be reached, the Secretary will publish a notice of closure in the *Federal Register* prohibiting all further JVP fishing in all or part of the regulatory area concerned.

The Council recommended that DAP equal TAC for each species category. Zero amounts are available for JVP. The Secretary concurs with the Council's recommendation, and has not established any JVP amounts. If future apportionments from DAP to JVP occur, the Secretary will also make the necessary determinations regarding PSC limits under § 672.20(c)(iv) at that time.

E. Halibut Prohibited Species Catch Limits

Pacific halibut PSC mortality limits are established and apportioned to trawl and fixed (hook-and-line and pot) gear that are equal to 2,000 mt and 750 mt mortality, respectively, by Amendment 18 to the FMP. The Secretary intends to use information that will be obtained from observers to extrapolate total bycatches of halibut by these two gear categories. Should this information prove inadequate for this purpose, the Secretary will project halibut bycatches using assumed rates, expressed as percentages in the tabulation below, for use in projecting when the 1990 halibut PSC limits might actually be reached during the fishing year. These bycatch

rates were used by the Council during its December 1989 meeting for purposes of examining effects of different groundfish harvest levels on halibut bycatch. These rates are subject to adjustment during the fishing year on the basis of the best available information, which might include actual rates during the fishery as observed and reported by NMFS-certified observers.

ASSUMED HALIBUT BYCATCH RATES, AS PERCENT OF TOTAL CATCH, BY DAP GEAR TYPE IN THE GULF OF ALASKA FOR PURPOSES OF MANAGING HALIBUT BYCATCHES IN 1990

	Bottom trawl	Mid-water trawl	Hook-and-line	Pot
Target species:				
Sablefish			8.0	0.4
Pacific cod			10.0	
Groundfish other than sablefish and Pacific cod	2.7	0.01		

Some halibut suffer mortality after being caught and discarded at sea. Rates of halibut mortality for the various DAP fisheries are assumed to be 50 percent of halibut caught with trawl gear, 13 percent of halibut caught with hook-and-line gear, and 12 percent caught with pot gear. The Secretary concurs with these estimates and hereby announces them for purposes of halibut management. Should new information become available during the year from the observer program or other sources, these rates may be revised. If so, new rates would be published in the *Federal Register*.

During the Council meeting, the representatives of fishermen using fixed gear and trawl gear expressed concern that the halibut PSC shares assigned to fixed and trawl gear could be taken prematurely in the 1990 fishing year, causing an early closure of the Gulf to either or both gear types. They requested the Council to recommend to the Secretary that an emergency rule be implemented under section 305(e) of the Magnuson Act that would allocate the PSC shares quarterly. If a gear type were to reach one-fourth of the assigned gear share early during a calendar quarter, further fishing by that gear would be prohibited for the remainder of the calendar quarter. In response, the Council recommended that the Secretary implement the emergency rule.

The Secretary has not yet taken action on the Council's recommendation. By way of this notice, fishermen are advised that any bycatches of halibut

caught since January 1, 1990 would be counted retroactively against quarterly allocations of halibut PSC should the Secretary implement an emergency rule to establish this measure.

(2) Inseason Adjustment in the Pollock Fishery

As indicated in the discussion, above, pollock stocks in the combined Western/Central Regulatory Area (W/C) are depressed. Stock assessments indicate a continued decline in pollock abundance during 1989 from peak abundance in 1981-1982. No significant recruitment has taken place since the strong 1978 and 1979 year classes entered the fishery as 3 year old fish in 1981 and 1982, respectively. Modeling results using bottom trawl survey data indicate the short term yields in 1990-1992 would range from about 74,000 to 84,000 mt, assuming that the strength of the 1987 year class is average. Most of the quota in 1989 was harvested from spawning populations located outside Shelikof Strait, which represents a change from prior years when roe pollock was harvested exclusively in Shelikof Strait. Considering uncertainties in stock condition, the Secretary has implemented for the 1990 fishing year an ABC of 70,000 mt for the W/C with a TAC equal to that amount.

The Council considered public testimony relevant to the status of pollock and its importance to local fishing communities as well as its importance to the groundfish fishing industry that depends economically on pollock in the Gulf of Alaska. The Council also considered the importance of pollock to northern sea lions, the abundance of which is low and believed to be declining. Because northern sea lions depend on pollock for food as a major part of their diet, the poor status of pollock might also be a contributing factor to the low abundance of northern sea lions.

The Council recommended that the Secretary implement an emergency rule under section 305(e) of the Magnuson Act to prevent overfishing pollock. The emergency rule, as recommended by the Council, would allocate quarterly the pollock TAC in the W/C such that no more than 25 percent of the pollock TAC in the W/C, including all of the Shelikof District TAC, would be available in the first quarter, and no more than 25 percent of the TAC, augmented by any portions that had not been harvested during preceding quarters, would be available during each of the subsequent three quarters. Any overruns of a quarterly apportionment would be subtracted from the subsequent

quarter's apportionment. The Eastern Regulatory Area TAC of 3,400 mt would not be allocated quarterly. Arithmetically, the following amounts will be allowed for harvest during each of the four quarters:

1st quarter = 11,250 (W/C) + 6,250 (Shelikof District); 2nd, 3rd, & 4th quarters = 17,500 (W/C) + uncaught amounts from previous quarters.

Quarterly apportionments would slow the fishery, because only 25 percent of the TAC would be available during the first quarter when the pollock roe fishery would normally occur. A smaller allowable harvest would attract fewer participants, especially as the much larger pollock fishery in the Bering Sea and Aleutian Islands area would occur at the same time. NMFS would be able to monitor harvest rates more accurately, and thus would be able to make better projections about when the four quarterly apportionments would be reached. The likelihood that any quarterly apportionments would be exceeded would be greatly reduced, and overfishing would be prevented. Not only would the status of pollock stocks be afforded more protection, but other marine life, including northern sea lions, that depend on pollock for food would also benefit. Finally, this action would allow fishery managers more time to evaluate pollock fishery data during the season, and to consider those data when determining whether additional protection must be afforded the pollock stocks.

The Secretary concurs with the need to prevent overfishing of pollock. Rather than implement an emergency rule, the Secretary is implementing an inseason adjustment of the fishing season for pollock under his authority at 50 CFR 672.22. Under paragraph (a) of this section, the Regional Director is authorized to close and open seasons in a management area if he determines that such action is necessary to prevent overfishing a stock of fish. The Regional Director will close the pollock directed fishing season in the W/C, including the Shelikof District, at 12:00 noon, Alaska local time, on a date during the first calendar quarter when the pollock harvest reaches 17,500 mt in the W/C and the Shelikof District combined.

Subsequently, he will reopen the fishing season for pollock at 12:00 noon Alaska local time during the second and third calendar quarters on April 1 and July 1, respectively. He will then close the pollock directed fishing season during each of these two quarters when the harvest reaches 25 percent of the TAC, or 17,500 mt, plus uncaught amounts from previous quarterly

apportionments, in the combined W/C, including the Shelikof District.

Because pollock bycatches will be counted against TAC, the Regional Director intends to manage the pollock harvest during the fourth quarter such that the total annual catch, including any bycatch amounts taken in other directed fisheries during the year, does not exceed TAC.

Under § 672.22(a)(2)(ii), the Regional Director has determined that the inseason adjustment selected is the least restrictive management measure necessary to prevent overfishing pollock stocks. Closures and openings of the pollock fishing season are the least restrictive management measure available, in that the entire TAC remains available for harvest without restricting other groundfish fisheries. Other measures he considered were (1) gear modifications that would protect pollock but still allow other fisheries to continue, and (2) closure of the W/C to all groundfish fishing.

The Regional Director rejected gear modifications as being impractical. No gear other than trawl gear is used in the pollock fishery. Trawl gear might be designed that would harvest only the very largest pollock, which are likely to succumb to natural mortality anyway. However, because medium sized pollock commingle with large pollock and are themselves a desirable part of the yield, all practical types of gear must effectively harvest mixed sizes. The Regional Director also rejected a total closure to all groundfish fishing. The sum of all TACs for all groundfish species in the W/C is about 268,000 mt, which would have an exvessel value of \$118 million at \$0.20 per pound if it is all harvested. To prohibit all groundfish fishing would cause severe economic harm.

The Regional Director considered all information relevant to the following factors in making the determinations required under paragraph (a)(2) of § 672.22:

1. *The effect of overall fishing effort within a regulatory area.* In 1989, the pollock fishery started about February 1, and ended on March 23 when the fishery was closed. The resulting harvest was 67,000 mt or 10 percent over TAC, and was harvested by 36 shorebased trawlers and 12 catcher/processor vessels. The fishery was directed at roe-bearing pollock, which had high exvessel value and attracted large amounts of harvesting and processing effort. Because so much effort is employed to harvest the pollock, even a day's fishing can result in gross overruns of the TAC. Slowing the fishing through quarterly apportionments will better

distribute the harvest, resulting in a more easily managed fishery and ensuring that overfishing is prevented.

2. *Relative abundance of stocks within the area.* Overall, pollock stocks are depressed. During the roe season, female roe-bearing pollock will concentrate in schools, which allows for fast, efficient harvests. Large amounts of pollock can be harvested within small areas. Exceeding TAC could occur, given the potential high rate of harvest.

3. *The condition of the stock within all or part of a regulatory area.* Information on the condition of pollock stocks is summarized above.

4. *Economic impacts on fishing businesses being affected.* As a result of this measure, only 25 percent of the TAC, or 17,500 mt, will be available for harvest in directed fisheries during the roe season that will occur in the first calendar quarter. The remaining pollock will be available for harvest in directed fisheries during the remaining three quarters. Although some vessel operators are able to target on female pollock, a 50/50 ratio between male and female pollock in the catch is assumed. Using this assumption, 8,750 mt of female pollock could be harvested. At a roe recovery rate of 7 percent, 612 mt of roe could be harvested. At a value of \$5 per pound, the industry could receive \$3.7 million, gross revenue, for this amount of roe. The balance of the quarterly apportionment resulting from male and female carcasses might be used in surimi production. If so, 3,850 mt of surimi could be produced from 17,500 mt of pollock at a recovery rate of 22 percent. At \$1 per pound, the industry could earn about \$3.5 million, gross revenue, for surimi. Under this action, the industry could earn a total of \$15.2 million during the first quarter from a combination of roe and surimi production. Other products could be produced during the period as well. Some roe production would occur during the first part of the second quarter as well.

Most of the remaining TAC, or 52,500 mt would be harvested during the non-roe season, mainly for surimi production when male and female pollock would be harvested. At a 22 percent recovery rate of surimi, this amount of pollock could be worth \$25 million gross revenue. The total value of roe and surimi production from the 70,000 mt TAC could be worth \$40.2 million.

Without this measure, the entire TAC would likely be harvested in a roe fishery. The extent that fishermen are able to target on schooling females affects the amount of roe that would be harvested. In a mixed fishery on males

and females together, only one-half the TAC would be females, or 35,000 mt. At a 7 percent recovery rate, 2,450 mt of roe might be harvested, which could be worth \$27 million to the fishermen.

Over the short term, the industry would earn additional gross revenue equal to the difference between \$40.2 and \$27 million, or \$13.2 million as a result of this inseason adjustment. Over the long term, pollock stocks are expected to increase in abundance, if overfishing is prevented, thereby increasing long term potential revenue.

Under § 672.22(b), if the Secretary decides for good cause that an inseason adjustment is to be made without affording a prior opportunity for public comment, public comments on the necessity for, and extent of, the adjustment will be received by the Regional Director for a period of 15 days after the effective date of this notice. Thus, public comments are invited on this inseason adjustment to allocate quarterly apportionments for pollock in the W/C for 15 days after January 26, 1990.

Public Comments

One letter of comments was received during the comment period on the

proposed specifications. Comments are summarized and responded to below.

Comment 1. Current PSC limits for Pacific halibut are adequate to constrain bycatches of Pacific halibut obviating the need to reduce available groundfish TACs.

Response: The Council did not recommend reductions in any of the groundfish species to reduce halibut bycatches. Any reductions of TAC from ABC are in response to domestic industry needs in directed fisheries.

Comment 2. Halibut bycatch rates should remain flexible to provide an incentive to fishermen to improve on the assumed rates.

Response: Information obtained from the observer program will be used inseason to upgrade halibut bycatch and mortality rates. Management dictated by these rates will be based on the best available information, including observer data.

Comment 3. The TAC for "other rockfish" should be 23,600 mt.

Response: The Council recommended, and the Secretary concurs, that the ABC should be no more than 17,700 mt. The Council did so to afford more protection to two components of the "other rockfish" species category, which are

rougheye and shortraker rockfish. Both species are low in abundance. Reducing the overall TAC will promote rebuilding of these two species.

Other Matters

This action is taken under § 611.92 and § 672.20 and complies with Executive Order 12291. The Secretary finds that implementing the inseason adjustment for pollock under § 672.22 without affording a prior opportunity for public comment or delaying its effective date is necessary to prevent overfishing of pollock stocks, which are in a depressed condition. This adjustment is effective January 26, 1990.

List of Subjects

50 CFR Part 611

Fisheries, Foreign relations, Reporting and recordkeeping requirements.

50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: January 25, 1990.

James E. Douglas, Jr.,

Acting Assistant Administrator for Fisheries,
National Marine Fisheries Service.

TABLE 1.—ABCs, INITIAL TACs, DAPS, JVPs, RESERVES, AND TALFFs OF GROUND FISH (METRIC TONS) FOR THE WESTERN/CENTRAL (W/C), WESTERN (W), CENTRAL (C), AND EASTERN (E) REGULATORY AREAS AND IN THE WEST YAKUTAT (WYK), SOUTHEAST OUTSIDE/EAST YAKUTAT (SEO/EYK), GULF-WIDE (GW), AND SOUTHEAST OUTSIDE (SEO) DISTRICTS OF THE GULF OF ALASKA

Species and Area ¹	ABC	TAC	Reserve	DAP	JVP	TALFF
Pollock:						
W/C.....	63,750	63,750	0	63,750	0	0
Shelikof.....	6,250	6,250	0	6,250	0	0
E.....	3,400	3,400	0	3,400	0	0
Total.....	73,400	73,400	0	73,400	0	0
Pacific cod:						
W.....	29,500	29,500	0	29,500	0	0
C.....	59,500	59,500	0	59,500	0	0
E.....	1,000	1,000	0	1,000	0	0
Total.....	90,000	90,000	0	90,000	0	0
Flatfish ² (deep-water):						
W.....	16,300	3,650	0	3,650	0	0
C.....	77,700	15,300	0	15,300	0	0
E.....	14,400	3,050	0	3,050	0	0
Total.....	108,400	22,000	0	22,000	0	0
Flatfish ³ (shallow water):						
W.....	30,200	3,570	0	3,570	0	0
C.....	52,200	6,180	0	6,180	0	0
E.....	2,100	250	0	250	0	0
Total.....	84,500	10,000	0	10,000	0	0
Arrowtooth flounder:						
W.....	27,000	4,450	0	4,450	0	0
C.....	141,000	23,170	0	23,170	0	0
E.....	26,600	4,380	0	4,380	0	0
Total.....	194,600	32,000	0	32,000	0	0

TABLE 1.—ABCs, INITIAL TACs, DAPS, JVPs, RESERVES, AND TALFFs OF GROUND FISH (METRIC TONS) FOR THE WESTERN/CENTRAL (W/C), WESTERN (W), CENTRAL (C), AND EASTERN (E) REGULATORY AREAS AND IN THE WEST YAKUTAT (WYK), SOUTHEAST OUTSIDE/EAST YAKUTAT (SEO/EYK), GULF-WIDE (GW), AND SOUTHEAST OUTSIDE (SEO) DISTRICTS OF THE GULF OF ALASKA—Continued

Species and Area ¹	ABC	TAC	Reserve	DAP	JVP	TALFF
Sablefish:						
W.....	3,800	3,770	0	3,770	0	0
C.....	11,800	11,700	0	11,700	0	0
WYK.....	4,600	4,550	0	4,550	0	0
SEO/EYK.....	6,000	5,980	0	5,980	0	0
Total.....	26,200	26,000	0	26,000	0	0
Other^{2,3} rockfish:						
W.....	4,300	4,300	0	4,300	0	0
C.....	7,700	7,700	0	7,700	0	0
E.....	5,700	5,700	0	5,700	0	0
Total.....	17,700	17,700	0	17,700	0	0
Pelagic⁴ shelf rockfish:						
W.....	1,400	1,400	0	1,400	0	0
C.....	5,800	5,800	0	5,800	0	0
E.....	1,000	1,000	0	1,000	0	0
Total.....	8,200	8,200	0	8,200	0	0
Demersal shelf rockfish⁵:						
SEO.....	Unknown	470	0	470	0	0
Thornyhead rockfish:						
GW.....	3,800	3,800	0	3,800	0	0
Other species⁶:						
GW.....	N/A	14,179	0	14,179	0	0
Total.....	606,800	297,749	0	297,749	0	0

¹ See figure 1 of § 672.20 for description of regulatory areas/districts.² The category "deepwater flatfish" means rex sole, Dover sole, and flathead sole.³ The category "shallow-water flatfish" means flatfish not including rex sole, Dover sole, flathead sole, or arrowtooth flounder.⁴ The category "other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat and East Yakutat Districts includes Slope rockfish and Demersal shelf rockfish. The category "other rockfish" in the Southeast Outside District includes Slope rockfish.⁵ The category slope rockfish includes *Sebastes polyspinis* (Northern rockfish), *S. alutus* (Pacific ocean perch), *S. aleuticus* (Rougheye), *S. zacentrus* (Sharpchin), *S. borealis* (Shortraker), *S. aurora* (Aurora), *S. melanostomus* (Blackgill), *S. goodei* (Chillipepper), *S. crameri* (Darkblotch), *S. elongatus* (Greenstriped), *S. variegatus* (Harlequin), *S. wilsoni* (Pygmy), *S. babcocki* (Red banded), *S. jordani* (Shortbelly), *S. diploproa* (Splitnose), *S. saxicola* (Stripetail), *S. miniatus* (Vermilion), and *S. reedi* (Yellowmouth).⁶ The category pelagic shelf rockfish includes *Sebastes melanops* (Black), *S. mystinus* (Blue), *S. ciliatus* (Dusky), *S. entomelas* (Widow), and *S. flavidus* (Yellowtail).⁷ The category demersal shelf rockfish includes *Sebastes paucispinis* (Bocaccio), *S. nebulosus* (China), *S. caurinus* (Copper), *S. maliger* (Quillback), *S. proriger* (Redstripe), *S. helvomaculatus* (Rosethorn), *S. brevispinis* (Silvergrey), *S. nigrocinctus* (Tiger), *S. ruberrimus* (Yelloweye), *S. pinningera* (Canary).⁸ The category "other species" includes Atka mackerel, sculpins, sharks, skates, eulachon, smelts, capelin, squid, and octopus. The TAC is equal to 5 percent of the TACs of the target species.[FR Doc. 90-2145 Filed 1-26-90; 10:37 am]
BILLING CODE 3510-22-M

50 CFR Parts 611 and 675

[Docket No. 91046-0006]

Foreign Fishing; Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure.

SUMMARY: The Director, Alaska Region, NMFS (Regional Director), has determined that the joint venture flatfish fisheries have attained their prohibited species catch (PSC) allowance of red king crab (50,000 crabs) in Zone 1 of the Bering Sea and Aleutian Islands (BSAI) area. Therefore, the Secretary of Commerce (Secretary) is prohibiting any further directed fishing for yellowfin sole, rock sole, and "other flatfish" in

Zone 1. This action is necessary to prevent excessive bycatch of red king crab in the trawl fishery for groundfish in an area of particular importance to the red king crab stock. This action is intended to carry out the objectives of the measures to control the bycatch of prohibited species in the trawl fishery for groundfish.

EFFECTIVE DATES: January 25, 1990 through December 31, 1990.

FOR FURTHER INFORMATION CONTACT: Janet E. Smoker (Fishery Management Biologist), NMFS, Alaska Region, P.O. Box 21668, Juneau, Alaska 99802-1668, telephone 907-586-7229.

SUPPLEMENTARY INFORMATION: The Secretary approved, on July 7, 1989, Amendment 12A to the Fishery Management Plan for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area (FMP) under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act).

Amendment 12A was implemented by the Secretary with a final rule promulgated August 9, 1989 (54 FR 32642) and effective September 3, 1989 through December 31, 1990.

The purpose of Amendment 12A is to limit incidental catches of the prohibited species Tanner crab, red king crab, and Pacific halibut by the groundfish fisheries in the BSAI area. Such incidental catches are referred to as bycatches in fisheries targeting other species. The amendment establishes five PSC limits, each of which are apportioned among four fisheries: the domestic annual processing (DAP) fisheries for flatfish and other species, and the joint venture processing (JVP) fisheries for flatfish and other species.

Each of the 20 PSC allowances prescribed for the 1990 groundfish fisheries appears in the initial specifications notice for 1990 for the BSAI area (55 FR 1434, January 16, 1990). The PSC allowances were based on the

anticipated bycatch of prohibited species derived by a mathematical prediction procedure, which used statistical information derived from fishery performance in previous years and projected performance for the 1990 fishing year. JVP quotas for species in the "other fisheries" categories were insufficient to allow directed fishing for those species. As a result, at the beginning of the 1990 season, the only JVP directed fisheries allowed were for yellowfin sole and other flatfish, and PSC allowances for the "other fisheries" were all set at zero. The PSC allowance for red king crab in Zone 1 for the JVP flatfish fisheries is 50,000 crabs.

Closure

The Regional Director has determined that the JVP flatfish PSC allowance for red king crab in Zone 1 has been reached. Under the regulation, when the PSC allowance for red king crab for the JVP flatfish fishery is reached, Zone 1 is closed to further directed fishing for yellowfin sole, other flatfish, and rock sole. JVP directed fishing for rock sole in the BSAI area was already closed due to insufficient availability of JVP quota.

Therefore, the Secretary, by this notice and under authority of § 675.21(c), prohibits for the remainder of the fishing year the receipt by foreign vessels of groundfish caught from Zone 1 (statistical areas 511, 512, and 516) that is composed of 20 percent or more in the aggregate of yellowfin sole, "other flatfish" and rock sole.

Classification

These actions are taken under §§ 675.20 and 675.21 and comply with Executive Order 12291.

List of Subjects in 50 CFR 675

Fisheries, reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 25, 1990.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 90-2210 Filed 1-26-90; 1:47 pm]

BILLING CODE 3510-22-M

50 CFR Part 672

[Docket No. 91050-0019]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure; request for comments.

SUMMARY: The Director, Alaska Region NMFS (Regional Director), has determined that the shares of the total allowable catch (TAC) for sablefish that will be allocated to trawl gear in the Gulf of Alaska for the 1990 fishing year are needed as bycatch amounts to support directed fisheries for other groundfish species. The Secretary of Commerce (Secretary) is prohibiting directed fishing for sablefish in the Gulf of Alaska with trawl gear during the 1990 fishing year. This action is a conservation measure that is necessary to prevent wastage of sablefish that would otherwise occur if sablefish quotas were reached prematurely. It is intended to carry out management objectives of the North Pacific Fishery Management Council for groundfish in the Gulf of Alaska.

EFFECTIVE DATES: Effective January 26, 1990; 1:47 p.m. Comments are invited until February 12, 1990.

ADDRESSES: Comments should be addressed to Steven Pennoyer, Director, Alaska Region (Regional Director), National Marine Fisheries Service, P.O. Box 21668, Juneau, Alaska 99802-1668.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION: This notice closes the directed sablefish by vessels using trawl gear in the Gulf of Alaska. Regulations pertaining to management of the Gulf of Alaska are at 50 CFR part 672. These regulations implement the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP).

Sablefish are caught in directed fisheries and are also caught incidentally while fishing for other groundfish species. Amounts of incidental catches of sablefish must be considered when managing total allowable catches (TACs) available in 1990. The Secretary established TACs for each of the target groundfish species, including sablefish, after having consulted with the North Pacific Fishery Management Council (Council), which met during December 5-8, 1989. The Council adopted TACs for each of the target species in the Gulf of Alaska and recommended that the Secretary implement these for the 1990 fishing year, which began January 1. For sablefish, the Council has recommended a Gulf of Alaska-wide TAC of 26,000 mt for the 1990 fishing year. Under § 672.24(b)(2), up to 20 percent of the sablefish TAC in the Central and

Western Regulatory Areas and up to 5 percent in the West Yakutat and Southeast Outside/East Yakutat Districts are allocated to trawl gear. Trawl gear will receive up to 3,620 mt of sablefish.

The Secretary has determined that fishermen, while fishing for other groundfish species, would catch incidentally all the sablefish amounts that are currently allocated to trawl gear in the Gulf of Alaska. If trawl fishermen engaged in directed fishing for sablefish, such amounts would not be available to support bycatch needs in other directed groundfish trawl fisheries. The Secretary expects fishermen, if not constrained, would conduct directed sablefish fishing early in the fishing year, and available sablefish quotas would be reached early. Subsequent sablefish catches would have to be discarded at sea as prohibited species. Discarding sablefish is a waste of a valuable resource contrary to Council's objectives. Any overharvesting of sablefish beyond the available quotas increases the risk of overfishing the sablefish resource.

Under § 672.24(b)(3)(i) of regulations governing the Gulf of Alaska fishery, if the Regional Director determines that the share of the sablefish TAC assigned to any type of gear and in any area or district is likely to be taken before the end of that year, the Secretary, in order to provide adequate bycatch amounts, will prohibit directed fishing for sablefish by persons using that type of gear for the remainder of the year by publishing a notice in the Federal Register.

To conserve the sablefish resource, the Secretary is prohibiting under § 672.24(b)(3)(i), directed fishing for sablefish, defined at § 672.2, in the Gulf of Alaska by operators of trawl vessels during the 1990 fishing year.

Public comments on this notice of closure may be submitted to the Regional Director at the address above until February 12, 1990.

Classification

This action is taken under § 672.24 and complies with Executive Order 12291.

List of Subjects in 50 CFR Part 672

Fisheries.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 25, 1990.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 90-2209 Filed 1-26-90; 1:47 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

(FI-105-88)

RIN 1545-AM55

Treatment of Certain Losses Attributable to Periods After October 31 of a Taxable Year of a Regulated Investment Company

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the Federal Register, the Internal Revenue Service is issuing temporary regulations relating to the treatment by a regulated investment company of a net capital loss, a net long-term capital loss, or of a net foreign currency loss attributable to periods after October 31 of a taxable year. The text of the temporary regulations also serves as the comment document for this notice of proposed rulemaking.

DATES: The regulations are proposed to be effective for, and be applicable to, taxable years of regulated investment companies ending after October 31, 1987. Written comments and requests for a public hearing must be delivered by April 2, 1990.

ADDRESSES: Send comments and requests for a public hearing to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attention: CC:CORP:T (FI-105-88), Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Lauren G. Shaw of the Office of Assistant Chief Counsel (Financial Institutions and Products), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention: CC:FI&P:2) or telephone 202-566-3828 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attention: IRS Reports Clearance Officer, T:FP, Washington, DC 20224.

The collections of information in this regulation are in 26 CFR 1.852-11T. This information is required by the Internal Revenue Service to effect an election provided by § 1.852-11T. This information will be used to verify that the appropriate amounts are included in taxable income for the proper taxable year. The likely respondents are businesses or other for-profit institutions.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances.

Estimated total annual reporting burden: 89 hours. The estimated annual burden per respondent varies from 10 minutes to 20 minutes, depending on individual circumstances, with an estimated average of 15 minutes.

Estimated number of respondents: 275.

Estimated frequency of responses: annually.

Background

The temporary regulations in the Rules and Regulations section of this issue of the Federal Register amend the Income Tax Regulations (26 CFR part 1) under section 852 of the Internal Revenue Code of 1986 to reflect certain amendments made to the Code by the Tax Reform Act of 1986 (Pub. L. 99-514; 100 Stat. 2085) and by the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647; 102 Stat. 3342). The temporary regulations are designated by a "T" following their section citation.

The final regulations which are proposed to be based on the temporary regulations would amend part 1 of title 26 of the Code of Federal Regulations. The regulations provide rules relating to the treatment by a regulated investment company of a net capital loss, a net long-term capital loss, or a net foreign currency loss attributable to periods after October 31 of a taxable year for purposes of determining taxable income, earnings and profits, and the amount which may be designated as capital gain dividends for a taxable year.

For the text of the temporary regulations see T.D. 8287 in the Rules and Regulations section of this issue of the Federal Register. The preamble to the temporary regulations provides a discussion of the rules.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Comments and Request for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably an original and eight copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the Federal Register.

Drafting Information

The principal author of these proposed regulations is Lauren G. Shaw of the Office of Assistant Chief Counsel (Financial Institutions and Products),

Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1.851-1—1.860-1

Income taxes, Investment companies, Real estate investment trusts.

26 CFR Part 602

Reporting and recordkeeping requirements.

Charles H. Brennan,

Acting Commissioner of Internal Revenue.

[FR Doc. 90-2221 Filed 1-30-90; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 218

RIN 1010-AB40

Regulations Governing Recoupment of Overpayments on Indian Leases

October 24, 1989.

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: The Royalty Management Program of the Minerals Management Service (MMS) is proposing to amend its regulations to codify longstanding policy restrictions with respect to recoupment of overpayments made by lessees and other payors on Indian leases. The established policy is that recoupments cannot exceed 50 percent of the current month's royalty revenues on allotted leases or 100 percent of the current month's royalty revenues on tribal leases.

DATES: Comments must be received on or before March 2, 1990.

ADDRESSES: Written comments regarding the proposed amendment should be mailed or delivered to the Minerals Management Service, Royalty Management Program, Rules and Procedures Branch, Denver Federal Center, Building 85, P.O. Box 25165, Mail Stop 662, Denver, Colorado 80225, Attention: Dennis C. Whitcomb.

FOR FURTHER INFORMATION CONTACT: Dennis C. Whitcomb, Chief, Rules and Procedures Branch (303) 231-3432. (FTS) 326-3432.

SUPPLEMENTARY INFORMATION: The principal author of this proposed rulemaking is Marvin D. Shaver of the Royalty Management Program, Rules

and Procedures Branch, Lakewood, Colorado.

I. Background

Royalty payments on production from mineral leases are a major source of income to many Indian allottees and, in some instances, the only source. Consequently, it has been a longstanding Department of the Interior policy that overpayments made by lessees and other royalty payors to Indians cannot be recovered by refund. This policy was established to prevent an undue financial burden on Indian allottees who may have limited financial means to refund the overpayment.

However, the current policy permits lessees and payors to recoup overpayments as a credit against future rental or royalty accruals due to Indian tribes or allottees. Lessees and operators were instructed to follow this recoupment policy in "Notice to Lessees and Operators of Indian Oil and Gas Leases No. 1A" (NTL-1A), issued by the Conservation Division of U.S. Geological Survey in 1977. Section IX of NTL-1A provides that in the case of tribal leases the credit must be against the same lease or, with approval of the tribe, accruals due under other tribal leases. In the case of allotted leases, such credits were subject to prior approval of the Bureau of Indian Affairs (BIA), with recovery of the overpayment pro rated over a period of time necessary to prevent an allottee's current monthly revenue being reduced by more than 50 percent.

This recoupment policy was adopted by MMS and included in Volume II of the Oil and Gas Payor Handbook by Addendum No. 12, effective December 1, 1983, and was also included in the revised Oil and Gas Payor Handbook issued in December 1986 (section 3.7, "Reporting Indian Overpayment Recoupments"). The policy is also included in the Solid Minerals Payor Handbook issued in September 1984 (chapter 5, "Recoupments on Indian Leases"). These payor handbooks have been provided to all royalty payors on Federal and Indian leases for specific guidance with respect to reporting requirements on oil and gas and solid minerals leases.

The MMS published revised final oil and gas product valuation regulations at 30 CFR part 206 on January 15, 1988 (53 FR 1184 and 53 FR 1230), effective March 1, 1988. Paragraph 206.150(e)(2) of the revised regulations terminated NTL-1A. However, the MMS policy and procedure remained in the payor handbooks.

II. Proposed Amendments

Although the Indian lease overpayment recoupment policy has been the same for many years, MMS believes that its regulations should state the policy. Consequently, MMS proposes to add new sections at 30 CFR 218.53 (previously reserved) and 30 CFR 218.203 to codify the policy and procedure described above. There may be situations where it would be desirable to recoup more than 50 percent of the net monthly revenues reported on an allotted lease. Therefore, the adopted amendments provide for the recoupment of more than 50 percent of the reported net monthly revenues with the approval of MMS and the concurrence of BIA.

The proposed rule would permit MMS to approve exceptions to the limitation on recoupments, for example, on leases where royalty payments are high, and where allowing larger recoupments would not be a financial burden to a particular Indian lessor. MMS expects to authorize this exception only in unusual circumstances. However, without the exception, there would be no flexibility in the rule to accommodate unexpected situations.

The proposed amendments are intended to provide more security for the Indian community and to provide MMS with regulatory authority for limiting the amount of authorized recoupments.

The Department's policy is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections regarding the proposed rule to the location identified in the **ADDRESS** section of this preamble. Comments must be received on or before the day specified in the **DATE** section of the preamble.

III. Procedural Matters

Executive Order 12291 and Regulatory Flexibility Act

The Department has determined that this document is not a major rule under E.O. 12291 and certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12630

The Department certifies that the proposed rule does not represent a governmental action capable of interference with constitutionally protected property rights. Thus, a Taking Implication Assessment need not be

prepared pursuant to Executive Order 12630, "Government Action and Interference with Constitutionally Protected Property Rights."

Paperwork Reduction Act of 1980

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act of 1969

The Department has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required under the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

List of Subjects in 30 CFR Part 218

Coal, Continental shelf, Electronic funds transfers, Geothermal energy, Government contracts, Indian lands, Mineral royalties, Natural gas, Penalties, Petroleum, Public lands-mineral resources, Reporting and recordkeeping requirements.

Dated: November 29, 1989.

Scott Sewell,

Deputy Assistant Secretary, Land and Minerals Management.

For the reasons set out in the preamble, 30 CFR part 218 is proposed to be amended as set forth below:

SUBCHAPTER A—ROYALTY MANAGEMENT

PART 218—COLLECTION OF ROYALTIES, RENTALS, BONUSES AND OTHER MONIES DUE THE FEDERAL GOVERNMENT

1. The authority citation for part 218 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.*; 25 U.S.C. 396a *et seq.*; 25 U.S.C. 2101 *et seq.*; 30 U.S.C. 181 *et seq.*; 30 U.S.C. 351 *et seq.*; 30 U.S.C. 1001 *et seq.*; 30 U.S.C. 1701 *et seq.*; 31 U.S.C. 9701; 43 U.S.C. 1301 *et seq.*; 43 U.S.C. 1331 *et seq.*; and 43 U.S.C. 1801 *et seq.*

2. Section 218.53 (previously reserved) under subpart B (Oil and Gas—General) is added to read as follows:

§ 218.53 Recoupment of overpayments on Indian leases.

Whenever an overpayment is made on an Indian lease, a payor may recoup the overpayment through a recoupment on Form MMS-2014. However, for any month a payor cannot recoup more than 50 percent of the net revenues reported in that month on an individual allotted lease, except as otherwise approved by MMS with the concurrence of BIA, or more than 100 percent of the net

revenues reported in that month on a tribal lease. A payor may request written permission from an overpaid tribe to recover monies against other leases owned by that tribe. MMS may approve a larger recoupment upon application from the payor. Proper procedures, as outlined in the MMS Oil and Gas Payor Handbook, are to be followed for reporting recoupments.

3. A new § 218.203 under Subpart E Solid Minerals—General is added to read as follows:

§ 218.203 Recoupment of overpayments on Indian leases.

Whenever an overpayment is made on an Indian lease, a payor may recoup the overpayment through a recoupment on Form MMS-4014. However, for any month a payor cannot recoup more than 50 percent of the net revenues reported in that month on an individual allotted lease, except as otherwise approved by MMS with the concurrence of BIA, or more than 100 percent of the net revenues reported in that month on a tribal lease. A payor may request written permission from an overpaid tribe to recover monies against other leases owned by that tribe. MMS may approve a larger recoupment upon application from the payor. Proper procedures, as outlined in the MMS Solid Minerals Payor Handbook, are to be followed for reporting recoupments.

[FR Doc. 90-2118 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-MR-M

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing receipt of a proposed amendment submitted by Indiana as a modification to the State's regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1979 (SMCRA). The amendment consists of proposed changes to the Indiana Surface Mining Statute provisions concerning reclamation of affected areas by any person not holding a valid permit; conflict of interest requirements applicable to the bureau of water and minerals resources advisory council; refund of bond pool entrance fees if an application is rejected; effective date of cessation

orders; and certain non-substantive changes.

This notice sets forth the times and locations that the Indiana program and the proposed program amendment will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed for the public hearing, if one is requested.

DATES: Written comments must be received on or before 4:00 p.m. on March 2, 1990; if requested, a public hearing on the proposed amendment is scheduled for 1:00 p.m. on February 26, 1990; and requests to present oral testimony at the hearing must be received on or before 4:00 p.m. February 15, 1990.

ADDRESSES: Written comments and requests to testify at the hearing should be directed to Mr. Richard D. Rieke, Director, Indianapolis Field Office, at the address listed below. If a hearing is requested, it will be held at the same address.

Copies of the Indiana program, the proposed amendment, a listing of any scheduled public meeting, and all written comments received in response to this notice will be available for public review at the following locations, during normal business hours Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Indianapolis Field Office, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204. Telephone: (317) 26-6166.

Indiana Department of Natural Resources, 608 State Office Building, Indianapolis, IN 46204. Telephone: (317) 232-1547.

Each requester may receive, free of charge, one single copy of the proposed amendment by contacting the OSM Indianapolis Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. Richard D. Rieke, Director, (317) 226-6166; (FTS) 331-6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982, *Federal Register* (47 FR 32107). Subsequent actions concerning the

conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Discussion of the Proposed Amendments

By letter dated December 4, 1989, (Administrative Record No. IND-0721), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program at Indiana Code (IC) 13-4-6 and IC 13-4.1-2, -6.5 and -11. The proposed amendment is contained in Indiana's 1989 Senate Enrolled Act 513 which was promulgated by the State on June 11, 1989. The IC 13-4 is limited to surface mining other than surface coal mining; therefore, the changes to IC 13-4 do not affect the approved Indiana surface coal mining program and will not be discussed here. The change to IC-13-4.1-2-2 adds language which would require the director of the IDNR to order any person who does not hold a valid permit to reclaim the affected area to required standards. Non-substantive changes are also proposed for IC-13-4.4.1-2-2. Changes to IC 13-4.1-2-3 would require each member of the bureau of water and minerals advisory council to file an annual statement of employment and financial interest and restricts their participation in proceedings to those where they do not have a direct or indirect financial interest.

Changes to IC 13-4.1-6.5-5 amends the bond pool fund proposal which has not yet been approved by the OSM. The amendment would make bond pool fund entrance fees refundable if the application to the fund is rejected.

The changes to IC 13-4.1-11-5 make certain non-substantive changes and add language that cessation orders are effective when served upon the permittee.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by IDNR satisfies the requirements of 30 CFR 732.15 for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Indiana program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking and include explanations in support of the commenter's recommendations.

Comments received after the time indicated under "DATES" or at locations other than the Indianapolis Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "FOR FURTHER INFORMATION CONTACT" by the close of business on February 15, 1990. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the Indianapolis Field Office by contacting the person listed under "FOR FURTHER INFORMATION CONTACT." All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed above under ADDRESSES. A summary of the meeting will be included in the Administrative Record.

List of Subjects in 30 CFR Part 914

Coal Mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: January 22, 1990.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 90-2166 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Coverage of Physician Assistant Services

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed amendment of rule.

SUMMARY: This proposed rule will amend DoD 6010.8-R (32 CFR part 199) which implements the Civilian Health and Medical Program of the Uniformed Services, providing for coverage of physician assistant (PA) services performed under supervision by physicians and billed by the supervising physician. The amendment provides authority for the payment of these services at appropriate rates below that of supervising and employing physicians, thereby enhancing the accuracy of payment as well as improving beneficiary access to health care.

DATES: Written public comments must be received on or before March 2, 1990.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Services, (OCHAMPUS), Office of Program Development, Aurora, CO 80045.

FOR FURTHER INFORMATION CONTACT: Joseph C. Rhea, Office of Program Development, OCHAMPUS, telephone (303) 361-3278.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the Federal Register on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)," as part 199 of this title. 32 CFR part 199 (DoD 6010.8-R) was reissued in the Federal Register on July 1, 1986 (51 FR 24008).

The CHAMPUS Regulation currently does not provide authorization for the billing and payment of services rendered by physician assistants. The Conference Report 100-1002, Defense Appropriation Act, FY 1989 discusses the use of non-physician health care providers by the Department of Defense and recommends that CHAMPUS begin a physicians assistant direct reimbursement demonstration project.

We have concluded that prior studies of physician assistants demonstrate the scope and quality of PA services, and provide adequate information on benefit coverage and payment mechanisms for these services by some third party payers including Medicare. These studies and a policy analysis (Health Technology Case Study 37 (December 1986) by the Office of Technology Assessment) recommend expansion of third party payment coverage for PA services. The studies demonstrate adequate education, certification, and licensure requirements are available and appropriately monitored by leading professional and provider organizations and state agencies.

We have determined that, as a matter of professional policy, physician assistants do not seek direct reimbursement for their services. Further, professional policy maintains the supervisory role of the physician; although supervision may be through remote contact as in the case of rural health clinics.

Extensive discussions and deliberations have resulted in the development of reimbursement policy for the services of physician assistants in Medicare by the Health Care Financing Administration. With minor modifications, we propose to use the same policy in payment for PA services rendered to CHAMPUS beneficiaries.

This proposed rule will have the impact of improving CHAMPUS beneficiaries' access to care while reducing the cost of selected services. It will not involve a significant additional administrative burden on CHAMPUS beneficiaries or providers of medical care. It is not, therefore, a "major rule" under Executive Order 12291.

Section 605(b) of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires that each federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. The Secretary certifies, pursuant to section 605(b) of title 5, United States code, enacted by the Regulatory Flexibility Act, that this regulation amendment will not have a significant impact on a substantial number of small businesses, organizations, or government jurisdictions.

List of Subjects in 32 CFR Part 199

Health insurance, Military personnel, Providers.

Accordingly, 32 CFR part 199, is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 10 U.S.C. 1079, 1086, 5 U.S.C. 301.

2. Section 199.6 is amended by redesignating paragraphs (c)(3) (iii) and (iv) as (c)(3) (iv) and (v), and adding a new paragraph (c)(3)(iii) to read as follows:

§ 199.6 Authorized providers.

(c) * * *

(3) * * *

(iii) *Certified physician assistant.* A physician assistant may provide care under general supervision of a physician. For purposes of CHAMPUS, a certified physician assistant is an individual who:

(A) Has satisfactorily completed a physician assistant's education program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation,

(B) Is currently certified by the National Commission on Certification of Physician Assistants, and

(C) Is currently in compliance with state licensure or certification requirements as required by the State in which the physician assistant is practicing.

4. Section 199.14 is amended by adding paragraph (h)(1)(iii) as follows:

§ 199.14 Provider reimbursement methods.

(h) * * *

(1) * * *

(iii) The allowable charge for physician assistant services other than assistant-at-surgery may not exceed 85 percent of the allowable charge for a comparable service rendered by a physician performing the service in a similar location. Cases in which the physician assistant and the physician perform component services of a procedure other than assistant-at-surgery (e.g., home, office or hospital visit), the combined allowable charge for the procedure may not exceed the allowable charge.

Dated: January 28, 1990.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 90-2127 Filed 1-30-90; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[OGD 05-90-01]

Special Local Regulations for Marine Events; Blue Angels Airshow; Approaches to Annapolis Harbor, Spa Creek, and Severn River, Annapolis, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing special local regulations for Blue Angels airshow and practice sessions to be held on May 26, 27, and 28, 1990, over the Severn River and the approaches to Annapolis Harbor. The effect of these regulations will be to restrict general navigation in the regulated area for the safety of spectators and participants. These regulations are needed to provide for the safety of life, limb, and property on the navigable waters during the event.

DATES: Comments must be received on or before March 19, 1990.

ADDRESSES: Comments be mailed or hand carried to Commander (bb), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004. The comments will be available for inspection and copying at room 209 of this address. Normal office hours are between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Phillips, Chief, Boating Affairs Branch, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004 (804) 398-6204.

SUPPLEMENTARY INFORMATION:

Interested persons are invited to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice (OGD 05-90-01) and the specific section of the proposal to which their comments apply. Reasons should be given for each comment. The regulations may be changed in light of comments received. All comments received before the expiration of the comment period will be considered before final action is taken on the proposal. No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to

make oral presentations will aid the rulemaking process. The receipt of comments will be acknowledged if a stamped self-addressed postcard or envelope is enclosed.

Drafting Information

The drafters of this notice are QM1 Kevin R. Connors, project officer, Boating Affairs Branch, Fifth Coast Guard District, and Lieutenant Steven M. Fitten, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Proposed Regulation

The U.S. Naval Academy is sponsoring this event, which will consist of six high performance jet aircraft flying at low altitudes in various formations over the Severn River. Federal Aviation Administration regulations require closing the waterway to vessel traffic as a prerequisite to issuing a permit for this event. Accordingly, the Commander, Fifth Coast Guard District, is issuing these regulations to close a portion of the Severn River to vessel traffic during the airshow and practice sessions. Closure of the waterway for any extended period is not anticipated, and commercial traffic should not be severely disrupted.

Economic Assessment and Certification

These proposed regulations are not considered either major under Executive Order 12291 on Federal Regulation or significant under Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979). Because closure of the waterway is not anticipated for any extended period, commercial marine traffic will be inconvenienced only slightly. The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. Since the impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

Federalism Assessment

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rulemaking does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Impact

This rulemaking has been thoroughly reviewed by the Coast Guard and it has

been determined to be categorically excluded from further environmental documentation in accordance with section 2.B.2.c of Commandant Instruction (COMDTINST) M16475.1B. A Categorical Exclusion Determination statement has been prepared and has been placed in the rulemaking docket.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 100 of title 33, Code of Federal Regulations as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary § 100.35-0501 is added to read as follows:

§ 100.35-0501 Approaches to Annapolis Harbor, Spa Creek, and Severn River, Annapolis, Maryland.

(a) *Definitions*—(1) *Regulated area*. The approaches to Annapolis Harbor, the waters of Spa Creek, and the Severn River, shore to shore, bounded on the south by a line drawn from Carr Point, at latitude 38°58'58.0" North, longitude 76°27'40.0" West, thence to Horn Point Warning Light (LLNR 17935), at 38°58'24.0" North, longitude 76°28'10.0" West, thence to Horn Point, at 38°58'20.0" North, longitude 76°28'27.0" West, and bounded on the north by a line drawn from Horseshoe Point, at latitude 38°59'47.0" North, longitude 76°29'34.3" West to Manresa Point at latitude 39°00'14.0" North, longitude 76°29'35.0" West.

(2) *Coast Guard Patrol Commander*. The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Group Baltimore.

(b) *Special Local Regulations*. (1) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the immediate vicinity on this area shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(ii) Proceed as directed by any commissioned, warrant, or petty officer.

(3) Any spectator vessel may anchor outside the regulated area specified in paragraph (a)(1) of these regulations but may not block a navigable channel.

(c) *Effective date*. These regulations are effective for the following periods:

1:30 p.m. to 6:30 p.m., May 26, 1990
11:30 a.m. to 5:00 p.m., May 27, 1990
12:30 p.m. to 5:00 p.m., May 28, 1990

Dated: January 23, 1990.

P.A. Welling,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 90-2133 Filed 1-30-90; 8:45 am]

BILLING CODE 4910-14-M

POSTAL RATE COMMISSION

39 CFR Part 3001

[Docket No. RM89-5]

Procedures for Consideration of Contract Rates; change in Date for Comments

January 25, 1990.

AGENCY: Postal Rate Commission.

ACTION: Notice of change in date for comments.

SUMMARY: The Commission published a request for comments in this proceeding on November 13, 1989 (54 FR 47223), specifying that such comments would be due 90 days following publication; i.e., February 12, 1990. Classroom Publishers Association, asserting an interest in the docket, has requested an eight-day extension of the comment period in order to permit its governing board to examine the matter at a regular meeting. Finding no prejudice from the granting of this short extension, the Commission is changing the due date to February 20, 1990.

DATES: The comments solicited by the notice published November 13, 1989, are now due on or before February 20, 1990.

ADDRESSES: Comments should be sent to Charles L. Clapp, Secretary of the Commission, Suite 300, 1333 H Street NW., Washington, DC 20268 (telephone: 202/789-6840).

FOR FURTHER INFORMATION CONTACT: David F. Stover, General Counsel, Postal Rate Commission, Suite 300, 1333 H Street NW., Washington, DC 20268 (telephone: 202/789-6820).

By the Commission.

Charles L. Clapp,

Secretary.

[FR Doc. 90-2146 Filed 1-30-90; 8:45 am]

BILLING CODE 7710-FW-M

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 51, 52, and 60**

[AD-FRL-3717-9]

Materials Separation Workshop**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of materials separation workshop.

SUMMARY: The EPA is conducting a workshop in which there will be a discussion among invited panelists and EPA representatives concerning the materials separation requirements in the new source performance standards (NSPS) and emission guidelines for municipal waste combustors that were proposed in the *Federal Register* on December 20, 1989 (54 FR 52209 and 52251). The workshop is open to the public to attend and observe the proceedings, but only the invited panelists will be given an opportunity to speak. The workshop is not a public hearing.

DATES: February 15, 1990.

ADDRESSES: The workshop will be held from 9 a.m. to 5 p.m. at the Sheraton National Hotel, Columbia Pike and Washington Boulevard, Arlington, Virginia. A block of rooms is being held at the hotel for attendees who wish to stay overnight at the workshop site. The hotel number is (703) 521-1900.

FOR FURTHER INFORMATION CONTACT: Fred L. Porter, Standards Development Branch, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-5251, FTS 629-5251.

SUPPLEMENTARY INFORMATION: On December 20, 1989, the Environmental Protection Agency (EPA) proposed new source performance standards (NSPS) for new municipal waste combustors (MWCs) and emission guidelines for existing MWCs (54 FR 52209 and 52251). Those *Federal Register* notices announced that an interactive forum would be scheduled in February 1990 to discuss the materials separation requirements in the proposed standards and guidelines. This forum, or "Materials Separation Workshop", will take place on February 15, 1990, between the hours of 9 a.m. and 5 p.m., at the Sheraton National Hotel in Arlington, Virginia.

The purpose of the Materials Separation Workshop is to provide an opportunity for invited panelists who are experienced in planning and implementing municipal solid waste

materials separation and recycling programs to share information and experiences with EPA. The information provided by participants in this workshop may be considered by EPA during the development of the final rule. The main topics to be discussed are the appropriateness and implementation of the proposed materials separation requirements, markets for separated materials, and financing implications of separation and recycling. The format of the workshop will be a discussion among the panelists and EPA representatives with the assistance of a facilitator who will pose questions for discussion and ensure that the workshop proceeds efficiently. It is important to note that the workshop is not a public hearing. (Public hearings were held on January 22-23 in Cambridge, Massachusetts; January 25-26 in Detroit, Michigan and January 30-31 in Seattle, Washington.) Therefore, although the workshop is open to the public to attend and observe the proceedings, there will be no oral presentations from anyone other than the invited panelists. The EPA recognizes that comments and questions by workshop observers and others may arise as a result of the workshop discussions and encourages the public to send them to Docket A-89-08 before the end of the public comment period (March 1, 1990). Written comments should be sent to Air Docket (LE-131), room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Dated: January 23, 1990.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 90-2071 Filed 1-30-90; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION**47 CFR Part 73**

[BC Docket No. 78-165, FCC 89-369; 37829]

Broadcast Service; Multiple Ownership Rules**AGENCY:** Federal Communications Commission.**ACTION:** Proposed rule; withdrawal.

SUMMARY: The Commission terminates without prejudice a proceeding (see Notice of Proposed Rule Making, 43 FR 31047, July 19, 1978) which proposed to apply, in part, the Commission's multiple ownership rules to noncommercial FM and/or television

stations. Given the significant amount of time that has elapsed since the initiation of the proceeding and the changes in the broadcast industry and in the Commission's regulations, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT:

Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:**Amendment of the Commission's Multiple Ownership Rules to Include Educational FM and TV Stations; Order**

Adopted: December 28, 1989.

Released: January 11, 1990.

By the Commission:

1. On June 7, 1978, the Commission adopted a Notice of Proposed Rule Making in the above entitled matter, 68 FCC 2d 831 (1978), proposing to apply in part, the Commission's multiple ownership rules to noncommercial FM and/or television stations. Specifically, the Notice questioned whether noncommercial stations should be considered under our rules (1) limiting the number of AM, FM, and television stations that an individual or entity may own on a national basis and (2) prohibiting the common ownership of two broadcast stations in the same service whose relevant contours overlap.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the significant amount of time that has elapsed since the initiation of this proceeding and in light of changes within the broadcasting industry and in the Commission's regulations themselves during this period, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record.

3. Accordingly, *it is ordered* that BC Docket No. 78-165 is terminated without prejudice.

4. The action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2113 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73**[BC Docket No. 81-705, FCC 89-370; 37830]****Broadcast Service; Retention of Letters From the Public****AGENCY:** Federal Communications Commission.**ACTION:** Proposed rule; withdrawal.

SUMMARY: The Commission terminates without prejudice a proceeding (*See* Notice of Proposed Rule Making, 46 FR 54787, November 4, 1981) which proposed to amend the Commission's rules requiring television and radio licensees to maintain, within their public inspection files, letters received from the public. Given the significant amount of time that has elapsed since the initiation of the proceeding and the changes in the broadcast industry and in the Commission's regulations, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

Amendment of the Commission's rules, § 73.1202, to Eliminate the Requirement that Licensees Retain Letters Received From the Public; Order

Adopted: December 27, 1989

Released: January 11, 1990.

By the Commission:

1. On October 1, 1981, the Commission adopted a Notice of Proposed Rule Making in the above entitled matter, 46 FR 54787 (Nov. 4, 1981), to amend the Commission's rules requiring television and radio licensees to maintain within their public inspection files letters received from the public.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the significant amount of time that has elapsed since the initiation of this proceeding and in light of changes within the broadcasting industry and in the Commission's regulations themselves during this period, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record.

3. Accordingly, *it is ordered* that BC Docket No. 81-705 *is terminated* without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2112 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73**[BC Docket No. 78-164, FCC 89-371; 37831]****Broadcast Service; Eligibility for Noncommercial Educational FM and TV Broadcast Licenses****AGENCY:** Federal Communications Commission.**ACTION:** Proposed rule; withdrawal.

SUMMARY: This action terminates without prejudice a proceeding (*see* the Notice of Inquiry, 43 FR 30842, July 18, 1978) which proposed amending Commission rules governing who is eligible to become a licensee of an educational FM or TV broadcast station. Given the significant amount of time that has elapsed since the initiation of the proceeding and the changes in the broadcast industry and in the Commission's regulations, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

Amendment of the Commission's Rules Governing the Eligibility for Noncommercial Educational FM and TV Broadcast Station Licenses; Order

Adopted: December 27, 1989.

Released: January 11, 1990.

By the Commission:

1. On June 7, 1978, the Commission adopted a Notice of Inquiry in the above entitled matter, 43 FR 30842 (July 18, 1978), to amend its rules governing who is eligible to become a licensee of an educational FM or TV broadcast station. This proceeding focused mainly on appropriately defining non-profit educational organizations.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the significant amount of time that has elapsed since the initiation of this proceeding and in light of changes within the broadcasting industry and in the Commission's regulations themselves during this period, we believe that it would not serve the public interest to attempt to resolve this

proceeding based on the existing record.¹

3. Accordingly, *it is ordered* that BC Docket No. 78-164 *is terminated* without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2111 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73**[MM Docket No. 85-192, FCC 89-372; 37836]****Broadcast Service; Single Majority Stockholder and Minority Incentive Provisions****AGENCY:** Federal Communications Commission.**ACTION:** Proposed rule; withdrawal.

SUMMARY: This action terminates without prejudice a proceeding (*see* the Notice of Proposed Rule Making, 50 FR 27629, July 5, 1985) which examined whether, and to what extent, the "single majority stockholder" exception to its ownership attribution standards and the "minority incentive" provisions of its multiple ownership rules may operate at cross-purposes. Because of pending litigation which raises issues regarding the constitutionality of the minority incentive provisions, the Commission has refrained from finalizing its order adopting these provisions. Until this order is finalized, it is premature to examine the interaction between the minority incentive provisions and the single majority stockholder exception. Given the significant amount of time that has elapsed since the initiation of this proceeding, the Commission finds that it would not serve the public interest to resolve this proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media

¹ We note that although we are terminating this proceeding we are not without guidelines to determine the eligibility of noncommercial educational station licensees. The Notice of Inquiry set forth the standards then used by the staff to process applications for noncommercial educational FM and television station licenses. We have applied those standards on an *ad hoc* basis during the pendency of this proceeding and will continue to utilize them to determine the eligibility of applicants for noncommercial educational facilities.

Bureau, Policy and Rules Division, 631-7792.

SUPPLEMENTARY INFORMATION:

Reexamination of the "Single Majority Stockholder" and "Minority Incentive" Provisions of § 73.3555 of the Commission's Rules and Regulations; Order

Adopted: December 27, 1989.

Released: January 11, 1990.

By the Commission:

1. On June 7, 1985, the Commission adopted a Notice of Proposed Rule Making in the above entitled matter¹ seeking comment on the interaction between the "single majority stockholder" exception to its ownership attribution standards² and the "minority incentive" provisions added to its national multiple ownership (or 12-12-12) rules.³ The Commission instructed the staff to prepare the present Notice at the time it adopted the "minority incentive" provisions to determine whether, and to what extent, the two provisions may operate at cross-purposes and what changes to the provisions might be warranted to remedy any conflict.⁴

2. The American Legal Foundation (ALF) filed a Petition for Reconsideration requesting that the Commission either delete the minority incentive provisions or reopen a rule making proceeding on the provisions. ALF also appealed the Commission's order adopting the minority incentive provisions in the U.S. Court of Appeals for the D.C. Circuit.⁵ That appeal is being held in abeyance pending Commission action on the ALF Petition. The Commission has not yet acted on the Petition because it raises issues regarding the constitutionality of the minority incentive provisions which are very similar to issues currently under litigation in *Winter Park Communications, Inc. v. FCC*, 863 F.2d 347, reh'g denied, Nos. 85-1755 and 85-1756 (D.C. Cir. June 21, 1989), cert. granted sub nom. *Metro Broadcasting, Inc. v. FCC*, No. 89-453 (January 8, 1990).

¹ Notice of Proposed Rule Making in MM Docket No. 85-192, FCC 85-303, 50 FR 27629 (July 5, 1985).

² See 47 CFR 73.3555, Note 2(b); § 76.501, Note 2(b) (1984); and Report and Order in MM Docket No. 83-46, 97 FCC 2d 997, 1008-09 (1984), recon. granted in part, 58 FR 2d 604 (1985), further recon. granted in part, 1 FCC Rcd 802 (1986).

³ See 47 CFR 73.3555(d); and Memorandum Opinion and Order in Gen. Docket No. 83-1009, 100 FCC 2d 74 (1985), appeal pending sub nom. *National Association of Black Owned Broadcasters v. FCC*, No. 85-1139 (D.C. Cir. filed March 4, 1985).

⁴ See Memorandum Opinion and Order, 100 FCC 2d at 95 n. 60.

⁵ See *National Association of Black Owned Broadcasters v. FCC*, No. 85-1139 (D.C. Cir. filed March 4, 1985).

The Commission believes that until it is able to finalize its order adopting the minority incentive provisions, it is premature to examine the interaction between the provisions and the single majority stockholder exception in this proceeding.

3. Moreover, in view of the significant amount of time that has elapsed since the initiation of this proceeding, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record. Therefore, we have determined that it should be dismissed without prejudice.

4. Accordingly, it is ordered that MM Docket No. 85-192 is terminated without prejudice.

5. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2110 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 80-757, FCC 89-373; 37832]

Broadcast Service; Automation of the Use of Measurement Data for AM Broadcast Stations

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Commission terminates without prejudice a proceeding (see Notice of Inquiry, 45 FR 82973, December 17, 1980) which proposed to amend the Commission's rules on the preparation and processing of the engineering portion of applications for AM broadcast stations from manual processing to automated processing. Given the significant amount of time that has elapsed since the initiation of the proceeding and the changes in the Commission's regulations, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATE: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

Amendment of the Rules Concerning Automation of the Use of Measurement Data for AM Broadcast Stations; Order

Adopted: December 27, 1989.

Released: January 11, 1990.

By the Commission:

1. On December 4, 1980, the Commission adopted a Notice of Inquiry in the above entitled matter, 45 FR 82973 (Dec. 17, 1980), to amend the rules pertaining to the preparation and processing of the engineering portion of applications for AM broadcast stations from manual processing to automated processing.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the time that has elapsed since the initiation of this proceeding, in light of changes in the Commission's regulatory processes during this period, and in view of the current scarcity of administrative resources to implement the proposed process if it were adopted, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record.

3. Accordingly, it is ordered that BC Docket No. 80-757 is terminated without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2107 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 85-299, FCC 89-374; 37833]

Broadcast Service; Distress Sale Policy

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; withdrawal.

SUMMARY: This action terminates without prejudice a proceeding (see Notice of Inquiry, 50 FR 42047, October 17, 1985) which examined the desirability of expanding the distress sale option to allow distress sales after the commencement of a revocation hearing. The Commission has refrained from acting in this proceeding until pending litigation related to the constitutionality of the distress sale policy is resolved. Given the significant amount of time that has elapsed since

the initiation of this proceeding, the Commission finds that it would not serve the public interest to resolve this proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

Distress Sale Policy of Broadcast Licensees; Order

Adopted: December 27, 1989.

Released: January 11, 1990.

By the Commission:

1. On October 8, 1985, the Commission adopted a Notice of Inquiry in the above entitled matter, 50 FR 42047 (1985), to explore the desirability of expanding the availability of the distress sale option which was intended to promote minority ownership in broadcasting. The proposed change would have permitted distress sales after the commencement of a revocation hearing.

2. On March 31, 1989, the U.S. Court of Appeals for the D.C. Circuit held that the Commission's distress sale policy was unconstitutional in *Shurberg Broadcasting of Hartford, Inc. v. FCC*, 876 F.2d 902, *reh'g denied*, 876 F.2d 953 (D.C. Cir. 1989), *cert. granted sub nom. Astroline Communications Co. v. Shurberg Broadcasting of Hartford, Inc.*, No. 89-700 (January 8, 1990). The Commission is refraining from acting in this proceeding until the constitutionality of the underlying policy is resolved. Given the time that has already elapsed since the initiation of this proceeding, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record. We have determined, therefore, that the proceeding should be terminated without prejudice.

3. Accordingly, *it is ordered* that MM Docket No. 85-299 is terminated without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,
Secretary.

[FR Doc. 90-2109 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 80-499, FCC 89-375]

Broadcast Service; Table of Television Channel Allotments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Commission terminates without prejudice a proceeding (*see* Notice of Proposed Rule Making, 45 FR 72901, November 3, 1980) which considered modifications in the process for making additional Very High Frequency (VHF) television allotments available. Given the significant amount of time that has elapsed since the initiation of the proceeding and issues arising in subsequent proceedings, the resolution of which must precede or would supersede the proposed modification, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

Table of Television Channel Allotments; Order

Adopted: December 27, 1989.

Released: January 11, 1990.

By the Commission:

1. On September 18, 1980, the Commission adopted a Notice of Proposed Rule Making in the above entitled matter, 83 FCC 2d 51 (1980), to consider modifications in the process for making additional Very High Frequency (VHF) television allotments available.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the significant amount of time that has elapsed since the initiation of this proceeding, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record. Moreover, the spectrum use issues that are under review in the advanced television/high definition television proceeding and the associated freeze on new television allotments have either superseded the proposals under review in this proceeding or require prior resolution. *See* Notice of Inquiry in MM Docket 87-268, 2 FCC Rcd 5125 (1987) and Tentative Decision and Further Notice of Inquiry in MM Docket 87-268, 3 FCC Rcd 6520 (1988).

3. Accordingly, *it is ordered* that BC Docket No. 80-499 is terminated without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2108 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 83-403, FCC 89-377; 37835]

Broadcast Service; Comparative Preferences Within Metropolitan Areas

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Commission terminates without prejudice a proceeding (*see* Notice of Proposed Rule Making, 48 FR 19428, April 29, 1983) which reviewed its policies concerning comparative preferences within metropolitan areas. Given the significant amount of time that has elapsed since the initiation of the proceeding and the changes in the broadcast industry and in the Commission's regulations, the Commission finds that it would not serve the public interest to resolve the proceeding based on the existing record.

DATES: This withdrawal is effective January 31, 1990.

FOR FURTHER INFORMATION CONTACT: Marilyn Mohrman-Gillis, Mass Media Bureau, Policy and Rules Division, 632-7792.

SUPPLEMENTARY INFORMATION:

The Commission's policy Pursuant to § 307(b) of the Communications Act of Granting Comparative Preferences Within Metropolitan Areas; Order

Adopted: December 28, 1989.

Released: January 11, 1990.

By the Commission:

1. On April 15, 1983, the Commission adopted a Notice of Proposed Rule Making in the above entitled matter, 48 FR 19428 (1983), to examine several of the Commission's policies concerning comparative preferences within metropolitan areas. Specifically, the proceeding proposed to allot channels to metropolitan areas, thereby permitting interested parties to apply for any municipality within that area without

receiving a comparative preference for specifying that municipality.

2. Upon a review of the status of this proceeding, we have determined that it should be terminated without prejudice. In view of the significant amount of time that has elapsed since the initiation of this proceeding and in light of changes within the broadcasting industry and in the Commission's regulations themselves during this period, we believe that it would not serve the public interest to attempt to resolve this proceeding based on the existing record.

3. Accordingly, *it is ordered* that MM Docket No. 80-403 is terminated without prejudice.

4. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Donna R. Searcy,
Secretary.

[FR Doc. 90-2106 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 94

[PR Docket No. 90-5, FCC 90-13]

Private Operational-Fixed Microwave Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has adopted a Notice of Proposed Rule Making to allow licensees in the Private Operational-Fixed Microwave Service (47 CFR part 94) to use certain channels in the 18 GHz band as the final link in the chain of distribution of video entertainment material. The Rules currently allow such transmissions only in the 2.5 GHz and 21.2 GHz bands. The Commission is also proposing that licensees transmitting video entertainment material in the 18 GHz band not be limited in the number of channels that they can use for this purpose. The action is proposed to encourage the more efficient utilization of sparsely used spectrum.

DATES: Comments are due on April 18, 1990, and replies to comments are due on May 21, 1990.

FOR FURTHER INFORMATION CONTACT: Michael A. Lewis, Private Radio Bureau, (202) 632-6940.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, PR Docket No. 90-5, adopted January 11, 1990, and released January 23, 1990. The full text of the Commission decision is available

for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington DC 20037.

Summary of Notice of Proposed Rule Making

1. This proceeding was initiated by a petition for rule making filed by Todd Integrated Systems, Inc (Todd). Todd noted that part 94 of the Commission's Rules restricts OFS licensees distributing video entertainment material on a point-to-point basis to frequencies greater than 21,200 MHz and limits licensees to four channels per transmitter location. Todd stated these restrictions do not meet the needs of satellite master antenna television operators (SMATV) operators and requested that the Commission allow channels in the 18 GHz band to be used as the final link in the chain of distribution of video entertainment material and that the four channel restriction be removed for licensees delivering video entertainment material.

2. Opponents to the Todd Petition stated that the 18 GHz band has been considered the primary replacement spectrum for those OFS licensees operating in the 12 GHz band that were displaced by the Commission's decision to reallocate the 12 GHz band to the Direct Broadcast Service. Opponents stated that allowing this new use of the 18 GHz band would reduce the utility of the band for the displaced licensees.

3. The Commission stated that it finds Todd's proposed use of the 18 GHz band compatible with the existing channelization of that band and that adoption of the proposals would further more efficient utilization of the spectrum. The Commission also stated that it would be inappropriate to continue reserving this spectrum for the displaced 12 GHz licensees because those licensees have had five years to relocate their operations. The Commission therefore proposed to allow the 6 MHz channels in the 18 GHz band to be used as the final link in the chain of distribution of video entertainment material. The Commission further proposed that licensees transmitting video entertainment material in the 18 GHz band not be restricted in the number of channels that they can receive for that purpose.

Regulatory Flexibility Act Initial Analysis

4. Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. 604, an initial regulatory flexibility analysis has been prepared. It is available for public viewing as part of the full text of this decision, which may be obtained from the Commission or its copy contractor.

Paperwork Reduction Act Statement

5. The proposals contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or recordkeeping, labeling, disclosure or record retention requirements, and will not increase burden hours imposed upon the public.

Lists of Subjects in 47 CFR Part 94

Radio, Private operational-fixed microwave service.

Rule Changes

47 CFR part 94 is proposed to be amended as follows:

PART 94—[AMENDED]

6. The authority citation for part 94 continues to read as follows:

Authority: Sections 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303, unless otherwise noted.

7. 47 CFR 94.9 is proposed to be amended by revising paragraphs (b)(2)(iii) and (b)(3) to read as follows:

§ 94.9 Permissibility of communications.

* * * * *

(b) * * *

(2) * * *

(iii) OFS licensees may deliver any of their own products or services to any receiving location in the frequency bands 6425-6525 MHz, 18142-18580 MHz, and on frequencies above 21,200 MHz.

(3) To provide the final link in the chain of transmission of program material to cable television systems, multipoint distribution systems, or master antenna TV systems, except in the frequency bands 6425-6525 MHz, 18142-18580 MHz and on frequencies above 21,200 MHz.

8. 47 CFR 94.15 is proposed to be amended by revising paragraph (g) to read as follows:

§ 94.15 Policy governing the assignment of frequencies.

* * * * *

(g) Except as provided in paragraph (h) of this section, applicants for frequencies below 21,200 MHz are limited to four transmit frequencies per band per transmitter site. Applicants for frequencies above 21,200 MHz are

limited to four transmit frequencies per path per transmit location. Further, master and remote stations using frequencies listed in § 94.65(a)(1) will not normally be authorized more than four (12.5 kHz) frequencies or frequency pairs. Licensees distributing multi-channel video entertainment material in the frequency band 18142-18580 MHz are not restricted in the number of channels that they may receive for that purpose.

9. 47 CFR 94.61 is proposed to be amended by revising the entry for the frequency band 17700 to 18580 MHz in the frequency table following paragraph (b) to read as follows:

§ 94.61 Applicability.

(b) * * *

Frequency Band (MHz)

17700-18580..... (6)(8)(10)(23)(27)

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2114 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 89-24; Notice 2]

Federal Motor Vehicle Safety Standards; Reopening of Public Comment Time

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Proposed rule; reopening of period for public comment.

SUMMARY: On December 5, 1989, (54 FR 50254) NHTSA published in the *Federal Register* a notice proposing an amendment to Motor Vehicle Safety Standard No. 108, Lamps, Reflective Devices, and Associated Equipment, to delete all references to "optical combinations" of lamps. The notice responded to a petition by the Truck Safety Equipment Institute (TSEI). In response to a request from TSEI, the comment period, which closed on January 19, 1990, is reopened until February 19, 1990.

DATES: Comments on the notice of proposed rulemaking must be received on or before February 19, 1990.

ADDRESSES: Comments should be submitted to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Kevin Cavey, Office of Rulemaking, NHTSA (202-366-5271).

SUPPLEMENTARY INFORMATION: On December 5, 1989, NHTSA published in the *Federal Register* a notice proposing three amendments of Motor Vehicle Safety Standard No. 108 to delete all references to "optical combinations" of lamps. This action was taken in response to a petition by TSEI. The due date for comments on the proposal was January 19, 1990.

TSEI filed a timely petition with the agency seeking an extension of the comment closing date. The engineering committee of TSEI has scheduled a meeting for January 24, 1990. In order that the committee may address the docket at its meeting, TSEI requested a 30-day extension of the closing date.

Because the notice of proposed rulemaking responds to a petition by TSEI, NHTSA believes that the comments of that organization on the proposal will be of particular interest in determining whether to proceed with rulemaking on the subject matter. The agency has decided to reopen the comment period for the time requested by TSEI. The comment closing date for the additional comment period is February 19, 1990.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

Authority: 15 U.S.C. 1392, 1407; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 25, 1990.

Barry Felice,

Associate Administrator for Rulemaking.

[FR Doc. 90-2174 Filed 1-30-90; 8:45 am]

BILLING CODE 4910-59-M

Notices

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ACTION

MiniGrants; Availability of Funds

AGENCY: Action.

ACTION: Notice of availability of funds.

SUMMARY: This notice announces the availability of funds for Fiscal Year 1990 under the ACTION MiniGrant Program authorized by the Domestic Volunteer Service Act of 1973, as amended (Pub. L. 93-113, title I, part C, 42 U.S.C. 4993).

The ACTION MiniGrant Program is intended to initiate, strengthen and/or supplement volunteer efforts and to encourage broad-based volunteer citizen participation which will develop and enhance community self-reliance. MiniGrants should be considered and used as a means to establish or strengthen activities and programs which demonstrate a solid potential for long-term effect.

Pursuant to MiniGrant Guidelines published in the Federal Register on October 12, 1984, (49 FR 40063), ACTION has established the MiniGrant funding priority for Fiscal Year 1990.

Projects for which MiniGrants will be considered will utilize non-stipended older youth or adult volunteers in a mentoring role, providing individualized illicit drug use prevention education and direct assistance to targeted low-income children and youth under 14 years old. Mentor volunteers will provide positive role models for the at-risk youth and will give of their time, knowledge and experience.

Mentors will guide the youth in positive activities for education, employment and recreation by creating and exploring with the youth opportunities for tutoring and remedial assistance, career and employment counseling, volunteer community service and sports and social activities. They will stress activities which increase the understanding of each child or youth about the community and his/her

responsibility as a citizen. The mentor will also interact with parents or guardians with the objective of improving their parenting skills and strengthening the family.

This mentoring support and prevention education and assistance should result in reducing the risk of these children and youth using illicit substances.

Match: All grants of \$3,500 or more awarded under this announcement require a minimum matching share of 10% (cash or in-kind) of the total grant cost, and a greater match is encouraged.

Eligibility: Public and private non-profit organizations which utilize, or will utilize, volunteers as an integral part of their provision of services may apply for grants.

Any applicant that does not adhere to a strict policy of the non-use of illicit drugs will not be eligible for consideration. Furthermore, an application will be ineligible if it refers to philosophy, proposed activities, training or educational materials that advocate the tolerance of the initial or responsible use of any illicit drug or the illicit use of any legal drug. This issue must be addressed in the application.

Pursuant to Public Law 101-204, preference will be given to applicants who have not previously received ACTION funding.

Awards: Subject to the availability of Fiscal Year 1990 funding, up to \$243,000 will be available for grants not to exceed \$9,000 each. Grant funding will be provided on a one-time, non-renewable basis for a budget period not to exceed one year.

Publication of this announcement does not obligate ACTION to award any specific number of grants, or to obligate the entire amount of funds available, or any part thereof.

Deadlines: One signed original and two copies of all completed applications must be submitted to the appropriate ACTION State Office, not later than 5 p.m. local standard time on March 30, 1990. Only those applications received at the appropriate office by the deadline will be eligible.

Application Review: ACTION's Program Demonstration and Development Division will review and evaluate all eligible applications submitted under this announcement. ACTION's Associate Director for Domestic and Anti-Poverty Operations

will make the final selection. ACTION reserves the right to ask for evidence of any claims of past performance or future capability.

General Criteria for Grant Review and Selection: Grant applications will be reviewed and evaluated based on the criteria outlined below, as appropriate, as well as conformance to the instructions included in the application.

1. Ability and plans to recruit, train and supervise non-stipended older youth or adult volunteers in a mentoring role, providing individualized illicit drug use prevention education and direct assistance to low-income children and youth under fourteen years old.

2. Ability and plans for mentor volunteers to guide the youth in positive activities for education, employment, community service, and recreation, and to increase the understanding of each child or youth about the community and his/her responsibility as a citizen.

3. Ability and plans for the mentor volunteers to interact with parents or guardians with the objectives of improving their parenting skills and strengthening the family.

4. Evidence of local community support for this particular project, including three letters of support from collaborating agencies and organizations which make a commitment to contribute to the value or success of the project.

5. Carefully formulated, measurable, time-phased objectives, including self-sufficiency, and feasibility of methods for meeting those objectives.

6. Potential for continuation of the activities and self-sufficiency of the program following the completion of the grant period supported by ACTION funds.

7. Innovative approach to combine federal and non-federal resources and volunteer participation, including potential for replication.

All grant applications must consist of:

a. Application for Federal Assistance (ACTION Form A-1036) with narrative budget justification and a narrative of project goals and objectives, and assurances.

b. Signed and dated: Certification Regarding Drug-Free Workplace Requirements.

c. Signed and dated: Certification Regarding Debarment, Suspension, and Other Responsibility Matters Primary Covered Transactions.

d. Current résumé of the candidate for the position of project director, if available, or the current résumé of the director of the applicant agency or project, and a job description of the project director position.

e. Organization chart of the applicant organization showing how the project is related to the organization and how participating affiliates are related to the organization.

f. List of the current board of directors showing their names, addresses and organizational and professional affiliations.

g. Three letters of support attesting to the applicant's ability to meet the criteria contained in section D and making a commitment to contribute to the value or success of the project.

h. CPA statement of accounting capability.

i. Articles of Incorporation.

j. Proof of non-profit status or an application for non-profit status, which should be made through documentation.

k. Statement that clearly identifies previous ACTION funding; identifying type of projects funded, periods of funding and amounts, or, a statement that applicant has not previously received funding from ACTION.

To receive an application package, please contact your ACTION State Office. Following is a list of ACTION Regional Offices, along with the addresses and telephone numbers of the ACTION State Program Offices under their jurisdiction.

Region I

Mr. John F. Torian, ACTION Regional Director, 10 Causeway Street, Rm. 473, Boston, MA 02222-1039, (617) 565-7000.

Mr. Romero A. Cherry, ACTION State Program Director, Abraham Ribicoff Federal Bldg., 450 Main Street, Rm. 524, Hartford, CT 06103-3002, (203) 240-3237.

Mr. Thomas E. Endres, ACTION State Program Director, U.S. Courthouse, Room 305, 76 Pearl Street, Portland, ME 04101-4188, (207) 780-3414.

Mr. Malcolm Coles, ACTION State Program Director, 10 Causeway Street, Rm. 473, Boston, MA 02222-1038, (617) 565-7000.

Mr. Peter Bender, ACTION State Program Director, Federal Post Office and Courthouse, 55 Pleasant Street, Room 223, Concord, NH 03301-3939, (603) 225-1450.

Mr. Vincent Marzullo, ACTION State Program Director, John O. Pastore Federal Bldg., Room 232, Two Exchange Terrace, Providence, Rhode Island 02903-1758, (401) 528-5424.

Region II

Ms. Suzanne Tufts, ACTION Regional Director, 6 World Trade Center, Room 758, New York, NY 10048-0206, (212) 466-3481.

Mr. Stanley Gorland, ACTION State Program Director, 402 East State Street,

District III, Room 426, Trenton, NJ 08608-1507, (609) 989-2243.

Mr. Bernard A. Conte, ACTION State Program Director, 6 World Trade Center, Room 758, New York, NY 10048-0206, (212) 466-4471.

Mr. Ruben Nazario, ACTION State Program Director, Federico DeGetau Federal Ofc Bldg., Carlos Chardon Avenue, Suite G-49, Hato Rey, PR 00917, (809) 766-5314.

Region III

Margaret Davison Matisko, ACTION Regional Director, U.S. Customs House, 2nd and Chestnut Street, Room 108, Philadelphia, PA 19106-2912, (215) 597-9972.

Betsy Irvin Wells, ACTION State Program Director, Federal Building Room 372-D, 600 Federal Place, Louisville, KY 40202-2230, (502) 582-6384.

Mr. Paul Schrader, ACTION State Program Director, LeVeque Tower, Room 304A, 50 W. Broad Street, Columbus, OH 43215-3301, (614) 469-7441.

Ms. Jean Taylor-Brown, ACTION State Program Director, 603 Morris Street—2nd Floor, Charleston, WV 25301-1409, (304) 347-5246.

Mr. Donald G. Lenz, Acting, ACTION State Program Director, U.S. Customs House, Room 108, 2nd and Chestnut Streets, Philadelphia, PA 19106-2998, (215) 597-3543.

Mr. Lindsay B. Scott, (Virginia and the District of Columbia), ACTION State Program Director, 400 North 8th Street, Room 1119, P.O. Box 10066, Richmond, VA 23240-1832, (804) 771-2197.

Mr. Jerry E. Yates, ACTION State Program Director, Federal Bldg., Room 1125, Box 257, 31 Hopkins Plaza, Baltimore, MD 21201-2814, (301) 962-4443.

Region IV

Mr. Jerome D. Ryans, ACTION Regional Director, 101 Marietta Street, NW.—Suite 1003, Atlanta, GA 30323-2301, (404) 331-2860.

Mr. John D. Timmons, ACTION State Program Director, Beacon Ridge Tower, Suite 770, 600 Beacon Parkway West, Birmingham, AL 35209-3109, (205) 731-1908.

Mr. Henry Jibaja, ACTION State Program Director, 3185 McCrory Street, Suite 115, Orlando, FL 32803, (407) 648-6117.

Mr. David A. Dammann, ACTION State Program Director, 75 Piedmont Avenue, NE., Suite 412, Atlanta, GA 30303-2587, (404) 331-4646.

Mr. Alfred E. Johnson, ACTION State Program Director, 265 Cumberland Bend Drive, Nashville, TN 37228-1890, (615) 736-5561.

Mr. Robert L. Winston, ACTION State Program Director, Federal Building, P.O. Century Station, 300 Fayetteville Street Mall, Room 131, Raleigh, NC 27601-1739, (919) 856-4731.

Mr. Arthur E. Brown III, ACTION State Program Director, Federal Bldg., Room 1005-A, 100 West Capitol Street, Jackson, MS 39269-1092, (601) 965-5664.

Mr. Jerome J. Davis, ACTION State Program Director, Federal Building, Room

872, 1835 Assembly Street, Columbia, SC 29201-2430, (803) 765-5771.

Region V

Ms. Cynthia Rudmann, Acting, ACTION Regional Director, 10 West Jackson Blvd.—6th Floor, Chicago, IL 60604-3964, (312) 353-5107.

Mr. James E. Braxton, ACTION State Program Director, 10 West Jackson Blvd.—6th Floor, Chicago, IL 60604-3964, (312) 353-8383.

Mr. Thomas L. Haskett, ACTION State Program Director, 46 East Ohio Street—Room 457, Indianapolis, IN 46204-1922, (317) 269-6724.

Mr. Joel H. Weinstein, ACTION State Program Director, Federal Building, Room 722, 210 Walnut St., Des Moines, IA 50309-2195, (515) 284-4818.

Mr. Stanley M. Stewart, ACTION State Program Director, Federal Bldg., Room 658, 231 West Lafayette Blvd., Detroit, MI 48226-2799, (313) 226-7848.

Mr. Peter A. Marks, ACTION State Program Director, 431 South 7th Street, Suite 2480, Minneapolis, MN 55415, (612) 784-4083.

Mr. Michael P. Murphy, ACTION State Program Director, 517 East Wisconsin Avenue, Rm. 601, Milwaukee, WI 53202-4507, (414) 291-1118.

Region VI

Ms. Beth Mahaffey Anderson, ACTION Regional Director, 1100 Commerce Street, Room 6B11, Dallas, TX 75242-0696, (214) 767-9494.

Mr. John J. McDonald, ACTION State Program Director, Federal Office Bldg., 911 Walnut, Room 1701, Kansas City, MO 64106-2009, (816) 426-5256.

Mr. Jerry G. Thompson, ACTION State Program Director, 611 East Sixth Street, Suite 107, Austin, TX 78701-3747, (512) 482-5671.

Mr. Robert J. Torvestad, ACTION State Program Director, Federal Bldg., Room 2506, 700 West Capitol Street, Little Rock, AR 72201-3291, (501) 378-5234.

Mr. James M. Byrnes, ACTION State Program Director, Federal Bldg., Room 248, 444 S.E. Quincy, Topeka, KS 66603-3501, (913) 295-2540.

Mr. Willard L. Labrie, ACTION State Program Director, 626 Main Street, Suite 102, Baton Rouge, LA 70801-1910, (504) 389-0471.

Mr. Ernesto Ramos, ACTION State Program Director, Federal Bldg., Cathedral Place, Suite 129, Santa Fe, NM 87501-2026, (505) 988-6577.

Mr. Zeke Rodriguez, ACTION State Program Director, 200 N.W. 5th Street, Suite 912, Oklahoma City, OK 73102-6093, (405) 231-5201.

Region VIII

Ms. Joyce Emerson, ACTION Regional Director, Executive Tower Bldg., 1405 Curtis Street, Suite 2930, Denver, CO 80202-2349, (303) 844-1070.

Mr. Ben Knopp, ACTION State Program Director, Columbine Bldg., Room 301, 1845 Sherman Street, Denver, CO 80203-1167, (303) 866-1070.

Mr. Ben Knopp, ACTION State Program Director, Federal Bldg., Room 8036, 2120 Capitol Avenue, Cheyenne, WY 82001-3649, (303) 722-2385.

Mr. Joe R. Lovelady, ACTION State Program Director, Federal Office Bldg., Drawer 10051, 301 South Park, Room 192, Helena, MT 59626-0101, (406) 449-5404.

Ms. Anne C. Johnson, ACTION State Program Director, Federal Bldg., Room 293, 100 Centennial Mall North, Lincoln, NE 68508-3896, (402) 437-5493.

Mr. John C. Pohlman, ACTION State Program Director (North/South Dakota), Federal Bldg., Room 213, 225 S. Pierre Street, Pierre, SD 57501-2452, (605) 224-5996.

Mr. Gary S. O'Neal, ACTION State Program Director, U.S. Post Office & Courthouse, 350 South Main Street, Room 484, Salt Lake City, UT 84101-2198, (801) 524-5411.

Region IX

Ms. Teresa Keeshan, ACTION Regional Director, 211 Main Street, Room 530, San Francisco, CA 94105-1914, (415) 484-3013.

Mr. Ricaro Gerakos, ACTION State Program Director, Federal Bldg., Room 14218, 11000 Wilshire Blvd., Los Angeles, CA 90024-3671, (213) 209-7421.

Mr. Michael J. Gale, ACTION State Program Director, Federal Bldg., P.O. Box 50024, Honolulu, HI 96850-0001, (808) 541-2832.

Mr. Steven P. Gordon, ACTION State Program Director, 4600 Kielzke Lane, Suite E-141, Reno, NV 89502-5033, (702) 784-5314.

Mr. Jess A. Sixkiller, ACTION State Program Director, 522 North Central, Room 205-A, Phoenix, AZ 85004-2190, (602) 379-4825.

Region X

Mr. John Keller, ACTION Regional Director, Suite 3039, Federal Office Building, 909 First Avenue, Seattle, WA 98174-1103, (206) 442-1558.

Mr. Stephen Neal Stivers, ACTION State Program Director, Federal Building, Room 647, 511 NW Broadway, Portland, OR 97209-3416, (503) 221-2261.

Mr. Jack R. Nunn, ACTION State Program Director, Alaska State Office, Suite 3039, Federal Office Building, 909 First Avenue, Seattle, WA 98174-1103, (206) 442-4975.

Mr. Wilford E. Overgaard, ACTION State Program Director, The Alaska Center, Suite 304, 1020 Main Street, Boise, ID 83702-5745, (208) 334-1707.

Mr. John A. Miller, ACTION State Program Director, Suite 3039, Federal Office Building, 909 First Avenue, Seattle, WA 98174-1103, (206) 442-4975.

Signed at Washington, DC this 26th day of January.

Jane A. Kenny,
Director.

[FR Doc. 90-2199 Filed 1-30-90; 8:45 am]

BILLING CODE 6050-28-M

AGENCY FOR INTERNATIONAL DEVELOPMENT

Public Information Collection Requirements Submitted to OMB for Review

The Agency for International Development (A.I.D.) submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of the entry no later than ten days after publication. Comments may also be addressed to, and copies of the submissions obtained from, the Reports Management Officer, John H. Elgin, (703) 875-1608, IRM/PE, room 1100B, SA-14, Washington, DC 20523.

Date Submitted: January 12, 1990.

Submitting Agency: Agency for International Development.

OMB Number: None.

Form Number: None.

Type of Submission: New.

Title: A.I.D. Contractor Employee Physical Examination Form.

Purpose: When A.I.D. hires contractor personnel for overseas assignments, the contractors are required to obtain a physician's certification that they are physically qualified to engage in the type of activity for which they will be employed. Physicians who do not regularly deal with patients going to lesser developed countries do not appreciate the difficulties of providing even the most basic medical services in many such areas. The form allows A.I.D. contractors to be screened by the State Department's Office of Medical Services (M/MED) prior to departure to insure the Mission or Embassy medical facility can meet special medical needs of the contractor. Thus the need for future medical evaluations would be reduced, since M/MED would find most existing medical problems that could not be dealt with locally and the individual would then most likely be denied approval to post.

Reviewer: Donald Arbuckle, (202) 395-7340, Office of Management and Budget, room 3201, New Executive Office Building, Washington, DC 20503.

Dated: January 12, 1990.

Wayne H. Van Vechten,

Planning and Evaluation Division.

[FR Doc. 90-2153 Filed 1-30-90; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Certain Coater Blade Steel; Short-Supply Review

AGENCY: Import Administration/International Trade Administration, Commerce.

ACTION: Notice of short-supply review and request for comments; certain coater blade steel.

Short-Supply Review Number: 4.

SUMMARY: Pursuant to section 4(b)(3)(B) of the Steel Trade Liberalization Program Implementation Act, Public Law No. 101-221, 103 Stat. 1886 (1989) ("the Act"), and § 357.104(b) of the Department of Commerce's Short-Supply Regulations, published in the Federal Register on January 12, 1990, 55 FR 1348 ("Commerce's Short-Supply Regulations"), the Secretary of Commerce ("Secretary") hereby announces that a short-supply determination is under review with respect to certain coater blade steel for use in the printing industry. On January 29, 1990, J.N. Eberle & Cie of Augsburg, Federal Republic of Germany, through the Commission of the European Communities, submitted an adequate petition to the Secretary requesting a short-supply allowance for 285 metric tons of this product. The Secretary has granted short-supply allowances for this product during each of the two immediately preceding years. Therefore, in accordance with section 4(b)(4)(B)(i)(II) of the Act and § 357.106(b)(1)(ii) of Commerce's Short-Supply Regulations, the Secretary will apply a rebuttable presumption that this product is presently in short supply. Unless domestic steel producers provide comments in response to this notice proving that they can and will produce and supply the requested quantity of this product within the desired period of time, provided it represents a normal order-to-delivery period, the Secretary will issue a short-supply allowance not later than February 13, 1990.

Comments: Interested parties wishing to comment on this review must send written comments not later than February 7, 1990, to the Secretary of Commerce, Attention: Import Administration, room 7866, U.S. Department of Commerce, Pennsylvania Avenue and 14th Street NW., Washington, DC 20230. All documents submitted to the Secretary shall be accompanied by four copies. Interested parties shall certify that the factual information contained in any

submission they make is accurate and complete to the best of their knowledge.

Any person who submits information in connection with a short-supply review may designate that information, or any part thereof, as proprietary, thereby requesting that the Secretary treat that information as proprietary. Information that the Secretary designates as proprietary will not be disclosed to any person (other than officers or employees of the United States Government who are directly concerned with the short-supply determination) without the consent of the submitter unless disclosure is ordered by a court of competent jurisdiction. Each submission of proprietary information shall be accompanied by a full public summary or approximated presentation of all proprietary information which will be placed in the public record. All comments concerning this review must reference the above noted short-supply review number.

FOR FURTHER INFORMATION CONTACT:

Richard O. Weible, Office of Agreements Compliance, Import Administration, U.S. Department of Commerce, room 7866, Pennsylvania Avenue and 14th Street NW., Washington, DC 20230, (202) 377-0159.

SUPPLEMENTAL INFORMATION: Pursuant to section 4(b)(3)(B) of the Act and § 357.104(b) of Commerce's Short-Supply Regulations, the Secretary hereby announces that a short-supply determination is under review with respect to certain coater blade steel. On January 29, 1990, the Secretary received an adequate short-supply petition from J.N. Eberle & Cie, through the Commission of the European Communities, under Article 8 of the Arrangement Between the European Coal and Steel Community and the European Economic Community, and the Government of the United States of America Concerning Trade in Certain Steel Products, for 285 metric tons of certain coater blade steel for use in the printing industry meeting the following specifications:

Width range: 2.5-4.25 inches;

Thickness range: 0.012-0.050 inch;

Straightness deviation: Maximum of 0.024 inch/10 feet of length;

Flatness: Extra accurate, with maximum deviation of 0.0025 inch/inch of width;

Other: High wear resistance, edge finish without notches, no surface defects, hardened and tempered, narrow tensile strength tolerances with maximum deviation ± 7 KSI.

Section 4(b)(4)(B)(i) of the Act and § 357.106(b)(1) of Commerce's Short-Supply Regulations require the

Secretary to make a determination with respect to a short-supply petition not later than the 15th day after the petition is filed if the Secretary finds that one of the following conditions exist: (1) The raw steelmaking capacity in the United States equals or exceeds 90 percent; (2) the importation of additional quantities of the requested steel product was authorized by the Secretary during each of the two immediately preceding years; or (3) the requested steel product is not produced in the United States. The Secretary finds that the importation of additional quantities of the requested steel product was authorized during each of the two immediately preceding years. Therefore, in accordance with section 4(b)(4)(B)(i)(II) of the Act and § 357.106(b)(1)(ii) of Commerce's Short-Supply Regulations, the Secretary is applying a rebuttable presumption that this product is presently in short supply. Unless domestic steel producers provide comments in response to this notice proving that they can and will produce and supply the requested quantity of this product within the desired period of time, provided it represents a normal order-to-delivery period, the Secretary will issue a short-supply allowance not later than February 13, 1990.

Dated: January 29, 1990.

Lisa B. Barry,

Acting Assistant Secretary for Import Administration.

[FR Doc. 90-2390 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Caribbean Fishery Management Council's Administrative Committee will hold a public meeting on February 9, 1990, at the Travelodge of Puerto Rico, Peace Talk Room, Isla Verde, San Juan, Puerto Rico.

The Administrative Committee will begin meeting at 9:30 a.m. to discuss the Caribbean Council's regular administrative matters, and also to discuss fishery management plan development.

For more information contact Miguel A. Rolon, Executive Director, Caribbean Fishery Management Council, Banco de Ponce Building, Suite 1108, Hato Rey, Puerto Rico 00918-2577; telephone: (809) 766-5926.

Dated: January 23, 1990.

David S. Crestin,

Deputy Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 90-2115 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Gulf of Mexico Fishery Management Council will hold a public meeting of its Limited Access Committee on February 7-8, 1990, at the Landmark Hotel, 2601 Severn Street, Metairie, LA. On February 7 the Committee will begin meeting at 8:15 a.m., and will recess at 5 p.m. On February 8 the meeting will reconvene at 8 a.m., and will adjourn at 2:30 p.m. The Committee will hear presentations on experiences with limited access systems, discuss the goals and objectives of the Committee, and also discuss general principles of Gulf limited entry programs.

For more information contact Wayne F. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 881, Tampa, FL; telephone: (813) 228-2815.

Dated: January 24, 1990.

David S. Crestin,

Deputy Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 90-2116 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council will hold a public meeting of an ad hoc committee to develop proposals for long-term management of the sablefish fishery. The meeting will be held on February 6-7, 1990, at the Metro Center, room 145, 2000 SW. First Avenue, Portland, OR. It will begin at 1 p.m., on February 6 and adjourn at noon on February 7. The committee will finalize a report that will be presented to the Pacific Council at the Council's March 8-9, 1990, public meeting in Seattle, WA.

For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 SW. First Avenue, Portland, OR 97201; telephone: (503) 326-6352.

Dated: January 26, 1990.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 90-2207 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries
Service, NOAA, Commerce.

The Pacific Fishery Management
Council will hold a public meeting of its
Groundfish Management Team (GMT),
on February 14-16, 1990, at the Mark O.
Hatfield Marine Science Center, room
MAL 136, Marine Science Drive,
Newport, OR. The GMT will review the
effects of the 1989 sablefish trawl trip
restrictions on the fishery, discuss
preliminary projections of the effects of
the current sablefish restrictions, as well
as discuss other topics pertaining to
commercial groundfish fisheries
management. The meeting will begin at
9 a.m., on February 14 and will adjourn
around noon on February 16.

For more information contact
Lawrence D. Six, Executive Director,
Pacific Fishery Management Council,
2000 SW. First Avenue, Portland, OR
97201; telephone: (503) 326-6352.

Dated: January 26, 1990.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 90-2208 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

South Atlantic Fishery Management Council; Closed Meeting

AGENCY: National Marine Fisheries
Service, NOAA, Commerce.

The South Atlantic Fishery
Management Council will hold a closed
meeting of the Advisory Panel Selection
Committee on February 5-6, 1990, at the
Town and Country Inn, 1540 Savannah
Highway, Charleston, SC. On February 5
the Committee will begin the meeting at
1:30 p.m., and will adjourn on February 6
at 5 p.m. The Committee will
reformulate and select new members to
the Billfish, King and Spanish Mackerel,
Law Enforcement, Snapper/Grouper,
Spiny Lobster, Swordfish, Habitat, and
Environmental Protection Advisory
Panels.

A general agenda will be available to
the public on or about January 31, 1990.
For more information contact Carrie R.F.

Knight, Public Information Officer, South
Atlantic Fishery Management Council,
One Southpark Circle, Suite 306,
Charleston, SC 29407, telephone: (803)
571-4366.

Dated: January 25, 1990.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 90-2117 Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

Endangered Species; Issuance of Permit; Anne Rudloe; Gulf Specimen Marine Laboratories, Inc. (P456)

On October 5, 1989, notice was
published in the *Federal Register* (54 FR
41132) that an application had been filed
by Ann Rudloe, of the Gulf Specimen
Marine Laboratories, Inc., P.O. Box 237,
Panacea, Florida 32346, for a permit to
take Kemp's ridley turtles (*Lepidochelys
kempii*) for scientific research.

Notice is hereby given that on January
8, 1990, as authorized by the provisions
of the Endangered Species Act of 1973,
the National Marine Fisheries Service
issued a Permit for the above taking,
subject to certain conditions set forth
therein.

Issuance of this Permit, as required by
the Endangered Species Act of 1973, is
based on the finding that such Permit:
(1) Was applied for in good faith; (2) will
not operate to the disadvantage of the
endangered species which is the subject
of the Permit; and (3) will be consistent
with the purposes and policies set forth
in section 2 of the Act. This Permit was
also issued in accordance with and is
subject to parts 220-222 of title 50 CFR,
of the National Marine Fisheries Service
regulations governing endangered
species permits.

The Permit is available for review in
the following offices:

Office of Protected Resources,
National Marine Fisheries Service, 1335
East West Hwy., room 7324, Silver
Spring, Maryland 20910; and

Director, Southeast Region, National
Marine Fisheries Service, 9450 Koger
Blvd., St. Petersburg, Florida 33702.

Dated: December 22, 1989.

Nancy Foster,

Director, Office of Protected Resources,
National Marine Fisheries Service.

[FR Doc. 90-2154; Filed 1-30-90; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has
submitted to OMB for clearance the
following proposal for collection of
information under the provisions of the
Paperwork Reduction Act (44 U.S.C.
chapter 35).

*Title, Applicable Form, and
Applicable OMB Control Number:*
Industrial Security Inspection Report;
DD Form 696; and OMB Control Number
0704-0014.

Type of Request: Reinstatement.

*Average Burden Hours/Minutes Per
Response:* 8.33 Hours.

Frequency of Response: Annually.

Number of Respondents: 12,453.

Annual Burden Hours: 168,674.

Annual Responses: 20,249.

Needs and Uses: The Industrial
Security Inspection Report is completed
in its entirety by DoD industrial security
representatives. It is used to assist in
arriving at a determination that DoD
contractors participating in the Defense
Industrial Security Program are
adequately safeguarding classified
information.

Affected Public: Businesses or other
for profit.

Frequency: Continuing.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Dr. J. Timothy
Sprehe.

Written comments and
recommendations on the proposed
information collection should be sent to
Dr. J. Timothy Sprehe at Office of
Management and Budget, Desk Officer,
room 3235, New Executive Office
Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Pearl
Rascoe-Harrison.

Written request for copies of the
information collection proposal should
be sent to Ms. Rascoe-Harrison, WHS/
DIOR, 1215 Jefferson Davis Highway,
Suite 1204, Arlington, Virginia 22202-
4302.

Patricia H. Means,

OSD Federal Register Liaison Officer,
Department of Defense.

[FR Doc. 90-2128 Filed 1-30-90; 8:45 am]

BILLING CODE 3810-01-M

Department of the Air Force**Community College of the Air Force; Meeting**

The Community College of the Air Force (CCAF) Board of Visitors will hold a meeting on Tuesday, 22 May 1990, at 8 am, Room C-138, White Hall (Building P-3), Chanute Air Force Base, Illinois.

Purpose of the meeting is to receive and discuss academic policies and issues relative to operation of CCAF. Agenda items include the Budget Forecast, Faculty Credentials, Base Closure Impact, Catalog Approval, and discussion on academic policies.

For further information contact Major David E. Muhleman, (205) 293-7937, Community College of the Air Force, Maxwell Air Force Base, Montgomery, Alabama, 36112-6655.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 90-2171 Filed 1-30-90; 8:45 am]

BILLING CODE 3910-01-M

DEPARTMENT OF EDUCATION**Notice of Proposed Information Collection Requests**

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Office of Information Resources Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before March 2, 1990.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Jim Houser, Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to George P. Sotos, Department of Education, 400 Maryland Avenue, SW., room 5624, Regional Office Building 3, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: George P. Sotos (202) 732-2174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early

opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Acting Director, Office of Information Resources Management, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from George Sotos at the address specified above.

Dated: January 26, 1990.

George P. Sotos,

Acting Director, for Office of Information Resources Management.

Office of Planning, Budget, and Evaluation

Type of Review: New Collection.

Title: Survey of Projects Funded by School Dropout Demonstration Assistant Program.

Frequency: Annually.

Affected Public: Individuals or households; State or local governments; Non-profit institutions.

Reporting Burden:

Responses: 3345

Burden Hours: 2554

Recordkeeping Burden:

Recordkeepers: 0

Burden Hours: 0

Abstract: The purpose of this study is to describe and evaluate demonstration projects funded by the School Dropout Demonstration Assistance Program. The Department uses this information to report to Congress.

[FR Doc. 90-2178 Filed 1-30-90; 8:45 am]

BILLING CODE 4000-01-M

[CFDA NO: 84.212A]**Fund for the Improvement and Reform of Schools and Teaching: Family-School Partnership Program; Notice Inviting Applications for New Awards for Fiscal Year 1990**

Purpose: To provide assistance to local educational agencies eligible to

receive a grant under chapter 1 of title I of the Elementary and Secondary Education Act, as amended, to conduct projects that increase the involvement of families in improving the educational achievement of their children

Deadline for Transmittal of Applications: 3/30/90.

Deadline for Intergovernmental Review: 5/29/90.

Application Available: 2/9/90.

Available Funds: \$4,000,000.

Estimated Range of Awards: \$50,000-\$200,000.

Estimated Average Size of Awards: \$125,000.

Estimated Number of Awards: 32.

Project Period: Up to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, and 85; and (b) The regulations for this program in 34 CFR part 758 as published in the *Federal Register* on May 2, 1989 (54 FR 18840).

Description of Competitions: This notice announces two competitions. The first is a general competition for which the Secretary intends to reserve approximately \$1,000,000. The second is a competition for selected priorities for which the Secretary intends to reserve approximately \$3,000,000. However, the allocation of funds between these two competitions may change depending on the number and quality of applications received.

General Competition: Under the general competition, applications proposing to conduct one or more of the activities under 34 CFR 758.4 will be considered. Within this general competition the Secretary is particularly interested in:

(a) Projects that demonstrate effective strategies for substantive involvement of parents in school-site management.

(b) Projects that demonstrate strategies for substantive involvement of parents, especially parents of Chapter I students, in educational choice programs.

However, under 34 CFR 75.105(c)(1) an application that meets the invitational priorities does not receive competitive or absolute preference over other applications in the general competition.

Competition for Selected Priorities: Under 34 CFR 758.4(a), (c) and (f) and 758.5(a) and 34 CFR 75.105(c)(3), the Secretary gives an absolute preference under this competition to applications that meet one or more of the following priorities:

(a) Projects that support the effort of families, through training and other means, to work with children in the

home both to attain the instructional objectives of the schools and instill positive attitudes toward education.

(b) Projects that train families, teachers, and other educational personnel in the LEA's schools to build an educational partnership between home and school.

(c) Projects that develop new school procedures and practices to meet the changing demographic characteristics and needs of families of school-age children.

Under 34 CFR 75.105(c)(3) the Secretary funds under this competition only applications that meet one or more of these absolute priorities.

General Considerations Applicable to Both Competitions: Under both competitions described above, the Secretary is particularly interested in projects that—

(a) Are planned, implemented, and evaluated with extensive parental involvement, including those groups of parents who traditionally have not been involved in their children's school activities;

(b) Demonstrate close cooperation with the Chapter 1 Program in participating schools and with its parent involvement components;

(c) Build on existing innovative family involvement programs in order to further develop, evaluate, and disseminate these programs;

(d) Demonstrate the applicant's financial commitment to the proposed project and show evidence of plans to continue the project after the grant ends; and

(e) Involve, where appropriate, students in private schools in the area served by the applicant.

However, under 34 CFR 75.105(c)(1) an application that meets these invitational priorities does not receive competitive or absolute preference over other applications.

For Applications or Information Contact: Elizabeth Vining, U.S. Department of Education, Fund for the Improvement and Reform of Schools and Teaching, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208-5524, telephone: (202) 357-6496.

Program Authority: 20 U.S.C. 4821-4823.

Dated: January 25, 1990.

Christopher T. Cross,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 90-2176 Filed 1-30-90; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No. 84.211B]

Fund for the Improvement and Reforms of Schools and Teaching: Schools and Teachers Program—School-Level Projects; Notice Inviting Applications for New Awards for Fiscal Year 1990

Purpose: To support school-level Schools and Teachers projects that improve educational opportunities for, and the performance of, elementary and secondary school students and teachers.

Deadline for Transmittal of Applications: 3/23/90.

Deadline for Intergovernmental Review: 5/20/90.

Applications Available: 2/9/90.

Available Funds: \$1,800,000.

Estimated Range of Awards: \$5,000-\$125,000.

Estimated Average Size of Awards: \$50,000.

Estimated Number of Awards: 30.

Project Period: Up to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, and 85; and (b) The regulations for this program in 34 CFR part 757 as published in the Federal Register on May 2, 1989 [54 FR 18840].

Priorities:

Absolute Priorities: Under 34 CFR 757.4 (b) and (k) and 757.5 (a) and (c), and 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications for school level projects conducted at an individual school or consortium of schools under the direction of a full time teacher or administrator that propose to conduct one or more of the following activities:

(a) Improve educational opportunities for, and the performance of, elementary and secondary school students and teachers by providing incentives for improved performance.

(b) Improve educational opportunities for, and the performance of, elementary and secondary school students and teachers by promoting individual responsibility and involvement in civic activities.

Under 34 CFR 75.105(c)(3) the Secretary funds under this competition only applications for school-level projects that meet one or both of these absolute priorities.

Competitive Preference: Within the absolute priorities, the Secretary gives competitive preference to applications that—

(a) Benefit students or schools with below-average academic performance;

(b) Lead to increased access to all students to a high quality education; and

(c) Develop or implement a system for providing incentives to schools, administrators, teachers, students or others to make measurable progress toward specific goals of improved educational performance.

Under 34 CFR 75.105(c)(2)(i), 34 CFR 757.5(b) and 757.20(d), the Secretary awards up to 25 points to an application that meets one or more of the competitive priorities in a particularly effective way. These points are in addition to any points the application earns under the selection criteria for this program (34 CFR 757.21).

Invitational Priorities: Within the absolute priorities, the Secretary is particularly interested in projects that—

(a) Build on the promising results of initial school-level restructuring efforts to which teachers and administrators have made demonstrable commitment;

(b) Reflect the involvement of parents, teachers, and administrators in the targeted school(s) in the planning, implementation and evaluation of the proposed project;

(c) Build collaborative relations between the elementary or secondary school and an institution of postsecondary education;

(d) Improve the school's capacity to serve more children in the regular classroom, rather than fragmenting services by providing special assistance only by referral outside the regular classroom or building; and

(e) Demonstrate the applicant's financial commitment to the proposed project and that show evidence of plans to continue the project after the grant ends.

In addition, for applications that address the second activity described in the Absolute Priorities section of this notice, the Secretary is particularly interested in applications that propose innovative approaches to character education.

However, under 34 CFR 75.105(c)(1) an application that meets one or more of the invitational priorities does not receive competitive or absolute preference over other applications that address the absolute priorities.

For Applications or Information Contact: Jennifer Mills, U.S. Department of Education, Fund for the Improvement and Reform of Schools and Teaching, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208-5524, Telephone: (202) 357-6496.

Program Authority: 20 U.S.C. 4811-4812.

Dated: January 25, 1990.
 Christopher T. Cross,
*Assistant Secretary for Educational Research
 and Improvement.*
 [FR Doc. 90-2177 Filed 1-30-90; 8:45 am]
 BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER90-138-000, et al.]

Oklahoma Gas & Electric Company, et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings
 have been made with the Commission:

1. Oklahoma Gas & Electric Co.

[Docket No. ER90-138-000]
 January 19, 1990.

Take notice that on January 5, 1990,
 Oklahoma Gas & Electric Company
 (OG&E) tendered for filing a Letter
 Agreement dated December 8, 1989 for
 the sale of replacement energy to
 Central Louisiana Electric Company
 (CLECO) for the year of 1990.

OG&E requests an effective date of
 January 1, 1990 for the service to
 commence and a waiver of the advance
 notice requirement.

Comment date: February 2, 1990, in
 accordance with Standard Paragraph E
 at the end of this Notice.

2. Selkirk Cogen Partners, L.P.

[Docket No. QF89-274-001]
 January 19, 1990.

On January 17, 1990, Selkirk Cogen
 Partners, L.P. (Applicant), of One
 Bowdoin Square, Boston, MA 02114,
 submitted for filing an application for
 recertification of a facility as a qualifying
 cogeneration facility pursuant to
 § 292.207 of the Commission's
 regulations. No determination has been
 made that the submittal constitutes a
 complete filing.

The topping-cycle cogeneration
 facility will be located in Selkirk, New
 York. The facility will consist of a
 combustion turbine generator, a
 supplementary fired heat recovery
 steam generator, and a non-condensing
 steam turbine generator. Thermal energy
 recovered from the facility will be sold
 to the General Electric Company for
 space heating and for use in the
 manufacture of plastics. The gross
 electric power production capacity of
 the facility will be 82.5 MW. The
 primary source of energy will be natural

gas. Construction of the facility is
 scheduled to begin February 15, 1990.

The certification for the original
 application was issued on September 28,
 1989 (48 FERC ¶ 62,228). The
 recertification is requested due to the
 following changes: (1) The ownership of
 the facility has been transferred from
 JMC Selkirk, Inc. to Selkirk Cogen
 Partners, L.P.; (2) The gross capacity has
 increased from 81 MW to 82.5 MW; and
 (3) The scheduled construction date has
 been changed from November 1989 to
 February 1990.

Comment date: Thirty days from
 publication in the Federal Register in
 accordance with Standard Paragraph E
 at the end of this notice.

3. Allegheny Power Service Corp.

[Docket No. ER90-156-000]
 January 19, 1990.

Take notice that on January 12, 1990,
 Allegheny Power Service Corporation
 on behalf of Monongahela Power
 Company and West Penn Power
 Company (the APS Parties) filed
 Modification No. 2 to the Power Resale
 Agreement between the APS Parties and
 Jersey Central Power and Light
 Company, Metropolitan Edison
 Company, and Pennsylvania Electric
 Company (The GPU Parties), which
 Modification increases the monthly
 demand charge payable by the GPU
 Parties to the APS Parties in accordance
 with §§ 4.12 and 4.13 of that Agreement.
 The proposed change is made in order to
 reflect increased costs to the APS
 Parties for providing the service to the
 GPU Parties. The APS Parties request
 waiver of notice to permit an effective
 date of March 1, 1990 for Modification
 No. 2.

Copies of the filing have been served
 upon the GPU Parties, the New Jersey
 Board of Public Utilities, the Public
 Utilities Commission of Ohio, the
 Pennsylvania Public Utility Commission,
 and the West Virginia Public Service
 Commission.

Comment date: February 2, 1990, in
 accordance with Standard Paragraph E
 at the end of this notice.

4. Cincinnati Gas & Electric

[Docket No. ER90-87-000]
 January 19, 1990.

Take notice that on January 17, 1990,
 Cincinnati Gas & Electric Company
 (CG&E) tendered for filing in this docket
 amended Rate Schedules and cost
 support relating to the charges levied by
 Dayton Power and Light Company
 (DP&L) to the Cincinnati Gas & Electric
 Company pursuant to the terms of the
 Interconnection Agreement dated
 January 1, 1979, between CG&E and

DP&L. DP&L states in this filing that it is
 renewing its request for a waiver of
 notice requirements so that the filing
 may become effective December 1, 1989.
 A copy of this filing was served upon
 the Cincinnati Gas & Electric Company.

Comment date: February 5, 1990, in
 accordance with Standard Paragraph E
 at the end of this notice.

5. Northern States Power Co. (Minnesota)

Northern States Power Co. (Wisconsin)
 [Docket No. ER90-160-000]
 January 19, 1990.

Take notice that Northern States
 Power Company-Minnesota and
 Northern States Power Company-
 Wisconsin, on behalf of themselves and
 the Wisconsin Public Power
 Incorporated System tendered for filing
 on January 16, 1990 a proposed long-
 term transmission service agreement
 among the parties. Under the proposed
 agreement Northern States Power
 Company-Minnesota and Northern
 States Power Company-Wisconsin
 would provide long-term transmission
 service for delivery power and energy
 from eastern Wisconsin of a portion of
 WPPI's ownership interest in the
 Boswell 4 generating station, and related
 services, for 35 years. NSP requests an
 effective date of 60 days after the date
 of the filing.

Copies of the filing were served upon
 WPPI and upon the Public Service
 Commissions of Minnesota and
 Wisconsin.

Comment date: February 5, 1990, in
 accordance with Standard Paragraph E
 at the end of this notice.

6. South Carolina Electric & Gas Co.

[Docket No. ER90-159-000]
 January 19, 1990.

Take notice that South Carolina
 Electric & Gas Company (SCE&G)
 tendered for filing on January 16, 1990,
 Seventeenth Sheet No. 5, and
 Seventeenth Revised Sheet No. 6, to its
 FERC Electric Tariff, Original Volume
 No. 1. These sheets contain proposed
 reductions to SCE&G's rates and
 charges to its municipal, rural electric
 cooperative and public power body
 sales-for-sale customers.

SCE&G proposes to place the revised
 tariff sheets containing the proposed
 rate reduction into effect on January 5,
 1990.

SCE&G states that the proposed rates
 would decrease revenues by
 approximately \$484,186 for the 12 month
 period ending November 30, 1989.

SCE&G states that the proposed
 decreased rate is necessitated by its last

approved Settlement Agreement with its municipal, rural electric cooperative and public power body sale-for-resale customers wherein this wholesale rate would track the Company's large general service rate.

Copies of the filing have been served upon SCE&G's jurisdictional customers and the South Carolina Public Service Commission.

Comment date: February 5, 1990, in accordance with Standard Paragraph E at the end of this notice.

7. Wisconsin Power & Light Co.

[Docket No. ER90-162-000]

January 19, 1990.

Take notice that on January 17, 1990, Wisconsin Power & Light Company (WPL) tendered for filing a wholesale power agreement dated December 4, 1989, between the Village of Gresham and WPL. WPL states that this new wholesale power agreement revises the previous agreement between the two parties which was dated June 20, 1962, and designated Rate Schedule No. 31 by the Commission.

The purpose of this new agreement is to revise the terms of service. Terms of service for this customer will be on a similar basis to the terms of service for the other W-3 wholesale customers.

WPL requests an effective date concurrent with the contract effective date be assigned. WPL states that copies of the agreement and the filing have been provided to the City of Plymouth and the Wisconsin Public Service Commission.

Comment date: February 5, 1990, in accordance with Standard Paragraph E at the end of this notice.

8. Arizona Public Service Co.

[Docket No. ER90-139-000]

January 19, 1990.

Take notice that on January 5, 1990, Arizona Public Service Company (APS) tendered for filing a revised Exhibit A increasing the Contract Demand under the Wholesale Power Supply Agreement with the Colorado River Indian Irrigation Project (APS-FERC Rate Schedule No. 65).

No changes from the currently effective Wholesale Power rate level are proposed herein. No new facilities or modifications to existing facilities are required to provide this service.

APS requests waiver of 18 CFR 35.11 to allow an effective date of November 1, 1989.

A copy of this filing has been served upon the Colorado River Indian Irrigation Project and the Arizona Corporation Commission.

Comment date: February 2, 1990, in accordance with Standard Paragraph E at the end of this notice.

9. Northwestern Public Service Co.

[Docket No. ES90-22-000]

January 22, 1990.

Take notice that on January 16, 1990, Northwestern Public Service Company (Applicant) filed an application seeking authority pursuant to section 204(a) of the Federal Power Act to issue first mortgage bonds in the principal amount not exceeding \$15 million via negotiated placement.

Comment date: February 15, 1990, in accordance with Standard Paragraph E at the end of this notice.

10. Cogen Technologies Linden Venture, L.P.

[Docket No. QF90-65-000]

January 22, 1990.

On January 3, 1990, Cogen Technologies Linden Venture, L.P. (Applicant), of 1600 Smith Street, Suite 5000, Houston, Texas 77002, submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations.

On January 11, 1990, Applicant filed a supplement to the January 3, 1990, application. Applicant states that its proposed cogeneration facility will also be comprised of approximately 8,500 feet of 345 kV transmission line which will be used to deliver the electric power output of the facility to Consolidated Edison's Goethals Substation on Staten Island, New York. In all other aspects, the application remains unchanged from that originally filed.

Comment date: Thirty days from publication in the Federal Register, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph:

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the

Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-2138 Filed 1-30-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP90-72-000]

Carnegie Natural Gas Co.; Filing

January 25, 1990.

Take notice that Carnegie Natural Gas Company ("Carnegie"), on January 19, 1990, tendered for filing on the above-captioned docket the following proposed revised tariff sheets to Second Revised Volume No. 1 of its FERC Gas Tariff:

Second Revised Sheet Nos. 133-138
Original Sheet Nos. 139 and 140

Carnegie states that these tariff sheets implement its proposal to track GSI Reservation Charges billed to Carnegie by Texas Eastern Transmission Corporation ("Texas Eastern") pursuant to Texas Eastern's Gas Supply Inventory Reservation Charge ("GSIRC") mechanism. Carnegie requests that these proposed tariff sheet be made effective as of November 1, 1989.

Carnegie explains in its filing that it originally filed the tracked charges billed to Carnegie through Texas Eastern's GSIRC in Docket No. RP89-253, which was filed on September 29, 1989. Carnegie states that the Commission rejected that original proposal, but did not preclude Carnegie from filing a more detailed and complete proposal to track GSIRC amounts billed to Carnegie by Texas Eastern. Carnegie views its filing as a filing in compliance with the Commission's order rejecting the tariff sheets.

Carnegie states in its application that it proposes to flow Texas Eastern GSI Reservation Charges through to its sales customers that purchase below 70% of their annual and monthly contract quantities. Carnegie refers to the tracking charge that it proposes to bill to its customers as a "GSI Flowthrough Charge." Carnegie states that its customers will be billed for deficient purposes applicable to a given month only if Texas Eastern bills a GSI Reservation Charge to Carnegie for that month. Carnegie's unit rate for its deficient customers in such months will be no more than Texas Eastern's GSI Unit Rate for that month. The exception to this direct billing tracker will arise, states Carnegie, if in a given month Carnegie incurs a GSI Reservation Charge from Texas Eastern because Carnegie purchased spot supplies in lieu of Texas Eastern supplies, and the unit

price of this spot gas plus the Texas Eastern GSI Unit Rate for that month is lower than Texas Eastern's commodity cost of gas for that month. In this instance, the GSI Reservation Charge amount incurred from Texas Eastern due to such low cost purchases will be flowed through Carnegie's PGA for the period such charges are incurred.

Carnegie further states that if Texas Eastern refunds GSI Reservation Charges to Carnegie in accordance with its GSIRC, Carnegie will distribute these refunds to those customers that paid GSI Flowthrough Charges to Carnegie. Carnegie also proposes an annual reconciliation procedure which will "true-up" obligations at the end of the contract year based on annual purchased deficiencies.

Carnegie states that its proposal is not an independent gas inventory charge mechanism, but it is designed solely to track through Texas Eastern's GSI Reservation Charges to those Carnegie customers who caused Carnegie to incur such charges.

Carnegie states that copies of the following were served upon the companies jurisdictional customers and applicable state commissions.

Any person desiring to protest said filing should file an intervention or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such interventions or protests should be filed on or before January 31, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-2139 Filed 1-30-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER90-24-000]

Commonwealth Atlantic Limited Partnership; Filing

January 25, 1990.

Take notice that on January 17, 1990, Commonwealth Atlantic Limited Partnership tendered for filing its Correction of Deficiencies to its October 17, 1989 filing in the above referenced docket.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal

Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before February 6, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-2136 Filed 1-30-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-132-011]

El Paso Natural Gas Co.; Compliance Tariff Filing

January 24, 1990.

Take notice that on January 19, 1990, El Paso Natural Gas Company ("El Paso") tendered for filing pursuant to part 154 of the Federal Energy Regulatory Commission's ("Commission") Regulations Under the Natural Gas Act, in compliance with ordering paragraph (B) of the "Order Denying Rehearing and Clarification" issued December 21, 1989 at Docket No. RP89-132-009, and in accordance with Order No. 500-H issued December 13, 1989 at Docket No. RM87-34-000, certain tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1.

El Paso states that by order issued December 21, 1989 at Docket No. RP89-132-009, the Commission, provided certain specific clarifications, but otherwise denied El Paso's request for rehearing and clarification of an August 1, 1989 order directing El Paso to refile its tariff sheets to, *inter alia*, remove certain vague language defining El Paso's buyout and buydown costs from § 21.2(b) of section 21. Take-or-Pay Buyout and Buydown Cost Recovery, contained in the General Terms and Conditions of its FERC Gas Tariff, First Revised Volume No. 1. In the December 21, 1989 order, the Commission stated that:

[T]he reason that El Paso filed the tariff language at issue was because of the March 31, 1989 sunset deadline. However, the Commission has now issued Order No. 500-H extending the deadline to December 31, 1990. Thus the issued raised in El Paso's rehearing request is moot. In light of this El Paso may not want to keep the originally proposed tariff language. Thus, El Paso should file revised tariff language to define its buyout/

buydown costs. Such language should be consistent with Order No. 500-H and the "known and measurable" standard.

Accordingly, El Paso tendered tariff sheets which reflect a revision to § 21.2(b) of said section 21 to incorporate the extended deadline for including buyout and buydown costs as promulgated by Order No. 500-H.

El Paso requested that the tendered tariff sheets be accepted by the Commission and permitted to become effective on February 18, 1990, which is thirty (30) days after the date of filing.

El Paso states that copies of the filing, except for the magnetic tape, were served upon all parties of record in Docket No. RP89-132-000 and, otherwise, upon all interstate pipeline system sales customers and shippers of El Paso and interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before January 31, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-2140 Filed 1-30-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-5-51-000]

Greak Lakes Gas Transmission Co.; Proposed Changes in FERC Gas Tariff Purchased Gas Adjustment Clause Provisions

January 24, 1990.

Take notice that Greak Lakes Gas Transmission Company ("Greak Lakes") on January 19, 1990 tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1.

First Revised Volume No. 1

First Revised Second Revised Substitute Twenty-Fifth

Revised Sheet No. 57(i)

First Revised Second Revised Substitute Twenty-Fifth

Revised Sheet No. 57(ii)

First Revised Second Revised Substitute Eleventh

Revised Sheet No. 57(v)

The tariff sheets reflected revised current PGA rates for the month of January, 1990. The tariff sheets were filed as an Out of Cycle PGA to reflect the latest estimated gas cost as provided to Great Lakes by its sole supplier of natural gas, TransCanada PipeLines Limited ("TransCanada"). These pricing arrangements were the result of contracts between each of Great Lakes' resale customers and the supplier.

Great Lakes requested waiver of the notice requirements of the provisions of § 154.309 of the Commission's Regulations and any other necessary waivers so as to permit the above tariff sheets to become effective as requested, in order to implement the gas pricing agreements between Great Lakes' resale customers and TransCanada on a timely basis.

Any person desiring to be heard or to protest said filing should file a Motion to Intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before January 31, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,
Secretary.

[FR Doc. 90-2141 Filed 1-30-90; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. PR90-1-000]

Nycotex Gas Transport; Petition for Rate Approval

January 24, 1990.

Take notice that on January 17, 1990, Nycotex Gas Transport (Nycotex) filed, pursuant to § 284.123(b)(2) of the Commission's regulations, a petition for rate approval requesting that the Commission approve as fair and equitable a maximum rate of 26.71 cents per MMBtu plus 1% fuel for transportation of natural gas under § 311(a)(2) of the Natural Gas Policy Act of 1978 (NGPA).

Nycotex's petition states that it is an intrastate pipeline within the meaning of section 2(16) of the NGPA and its system consists of approximately 124 miles of mainline and appurtenant facilities in Cabell, Putnam and Jackson Counties, West Virginia.

Pursuant to § 284.123(b)(2)(ii), if the Commission does not act within 150 days of the filing date, the rate will be deemed to be fair and equitable and not in excess of an amount which interstate pipelines would be permitted to charge for similar transportation service. The Commission may, prior to the expiration of the 150 day period, extend the time for action or institute a proceeding to afford parties an opportunity for written comments and for the oral presentation of views, data and arguments.

Any person desiring to participate in this rate proceeding must file a motion to intervene in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedures. All motions must be filed with the Secretary of the Commission on or before February 13, 1990. The petition for rate approval is on file with the Commission and is available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 90-2142 Filed 1-30-90; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. TA90-1-6-001]

Sea Robin Pipeline Co., Compliance Filing

January 24, 1990.

Take notice that on January 16, 1990, Sea Robin Pipeline Company (Sea Robin) filed with its proposal for the disposition of the FERC Account No. 191 balance at April 1, 1990. Sea Robin states that the balance will contain (1) either the over or under recovery of gas costs resulting from the amortization of the Account No. 191 balance by the surcharge in effect pursuant to the December 29 order (Account No. 191 balance accumulated January 1, 1989–August 31, 1989) and (2) any deferred gas cost (debit or credit) accumulated from September 1, 1989 through March 31, 1990.

Sea Robin also states that the letter is being served on all parties listed on the official service lists established by the Secretary for all affected proceedings, as well as on all necessary persons under Rule 602(d)(ii).

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211 (1989)). All such protests should be filed on or before January 31, 1990. Protests will be considered by the Commission in

determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 90-2143 Filed 1-30-90; 8:45 am]
BILLING CODE 6717-01-M

Office of Conservation and Renewable Energy

Energy Conservation Program for Consumer Products; Application for Interim Waiver and Petition for Waiver of Furnace Test Procedures From Rheem Manufacturing Company (F-019)

AGENCY: Conservation and Renewable Energy Office, Department of Energy.

SUMMARY: Today's notice publishes a letter granting an Interim Waiver to Rheem Manufacturing Company (Rheem) from the existing Department of Energy (DOE) test procedures for furnaces regarding blower time delay for Rheem's GDE(–) up-flow models and GLE(–) down-flow models of induced draft furnaces.

Today's notice also publishes a "Petition for Waiver" from Rheem. Rheem's Petition for Waiver requests DOE to grant relief from the DOE test procedures relating to the blower time delay specification. Rheem seeks to test using a blower delay time of 30 seconds instead of the specified 1.5 minute delay between burner on-time and blower on-time. DOE is soliciting comments, data, and information respecting the Petition for Waiver.

DATES: DOE will accept comments, data, and information not later than March 2, 1990.

ADDRESSES: Written comments and statements shall be sent to: Department of Energy, Office of Conservation and Renewable Energy, Case No. F-019, Mail Stop CE-132, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasser, U.S. Department of Energy, Office of Conservation and Renewable Energy, Mail Station CE-132, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9127
Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-12, Forrestal

Building, 1000 Independence Avenue,
SW., Washington, DC 20585, (202)
586-9507

Background

The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act (EPCA), Public Law 94-163, 89 Stat. 917, as amended by the National Energy Conservation Policy Act (NECPA), Public Law 95-619, 92 Stat. 3266, the National Appliance Energy Conservation Act of 1987 (NAECA), Public Law 100-12, and the National Appliance Energy Conservation Amendments of 1988 (NAECA 1988), Public Law 100-357, which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at 10 CFR part 430, subpart B.

DOE has amended the prescribed test procedures by adding 10 CFR 430.27 on September 26, 1980, creating the waiver process. 45 FR 64108. DOE further amended the Department's appliance test procedure waiver process to allow the Assistant Secretary for Conservation and Renewable Energy (Assistant Secretary) to grant an interim waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. 51 FR 42823, November 26, 1986.

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of a waiver.

The interim waiver provisions, added by the 1986 amendment, allow the Assistant Secretary to grant an interim waiver when it is determined that the applicant will experience economic hardship if the Application for Interim Waiver is denied, if it appears likely that the petition for waiver will be granted, and/or the Assistant Secretary

determined that it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver.

On September 29, 1989, Rheem filed an Application for an Interim Waiver regarding blower time delay. Rheem's application seeks an interim waiver from the DOE test provisions that require a 1.5 minute time delay between the ignition of the burner and starting of the circulating air blower. Instead, Rheem requests the allowance to test using a 30 second blower time delay when testing its model GDE(-) and GLE(-) induced draft furnaces. Rheem states that the 30 second delay is indicative of how these furnaces actually operate. Such a delay results in an energy savings of approximately 0.6 percent. Since current DOE test procedures do not address this variable blower time delay, Rheem asks that the interim waiver be granted.

Previous waivers for this type of timed blower delay control have been granted by the Department to the Coleman Company, 50 FR 2710, January 18, 1985, the Magic Chef Company, 50 FR 41553, October 11, 1985, the Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, and the Trane Company, 54 FR 19226, May 4, 1989. Thus, it appears likely that the Petition for Waiver will be granted for blower time delay.

Because Rheem's Petition for Waiver requesting relief from the DOE test procedures concerning blower time delay appears likely to be granted, Rheem's Application for Interim Waiver on these subjects is granted.

Pursuant to paragraph (b) of 10 CFR 430.27, DOE is hereby publishing the "Petition for Waivers" in its entirety. The petition contains no confidential information. DOE solicits comments, data, and information respecting the petition.

In addition, pursuant to paragraph (e) of § 430.27 of the Code of Federal Regulations, the following letter granting the Application for Interim Waiver was issued to Rheem Manufacturing Company.

Issued in Washington, DC, January 25, 1990.

J. Michael Davis,

Assistant Secretary, Conservation and Renewable Energy.

January 25, 1990.

Mr. Daniel J. Canclini, Vice President, Rheem Manufacturing Company, 5600 Old Green Wood Road, P.O. Box 6444, Fort Smith, AR 72906-0444

Dear Mr. Canclini: This is in response to your September 29, 1989, Application for Interim Waiver and Petition for Waiver from the Department of Energy (DOE) test

procedures for furnaces when testing the company's GDE(-) and GLE(-) gas-fueled forced-air induced draft furnaces regarding blower time delay.

Pursuant to the Energy Policy and Conservation Act, as amended, the Department has prescribed test procedures to measure the energy consumption of certain major household appliances, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchase decisions. These test procedures appear in the Code of Federal Regulations at 10 CFR part 430, subpart B.

DOE amended the test procedure regulations on September 26, 1980 [45 FR 64108] and November 26, 1986, [51 FR 42823] by adding paragraph 430.27. These provisions allow the Assistant Secretary for Conservation and Renewable Energy to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing of the basic model according to the prescribed test procedures or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inadequate comparative data. The 1986 amendments added provisions allowing the Assistant Secretary to grant an interim waiver for a particular basic model when a petitioner demonstrates the likely success of the petition for waiver, it is determined that the applicant will experience economic hardship if the Application for Interim Waiver is denied and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver.

Previous waivers for timed blower delay control have been granted to the Coleman Company, 50 FR 2710, January 18, 1985, Magic Chef Company, 50 FR 41553, October 11, 1985, Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, and the Trane Company, 54 FR 19226, May 4, 1989.

Rheem's Application for Interim Waiver does not provide sufficient information for the Department to evaluate what, if any, economic impact or competitive disadvantage Rheem will likely experience absent a favorable determination on the application for interim waiver. Rheem feels that its competitive position in the marketplace would be compromised if this Application for Interim Waiver is not granted. However, the Department finds that it would be desirable for public policy reasons to grant Rheem's Application for Interim Waiver. Specifically, in those instances where the likely success of the petition for waiver has been demonstrated based upon DOE having granted a waiver for a similar product design, it is in the public's interest to have the similar products tested and rated for energy consumption on a comparable basis.

Therefore, Rheem's Application for an Interim Waiver requesting a change from the DOE test procedures for its GDE(-) and GLE(-) gas-fueled forced-air induced draft

furnaces regarding blower time delay is granted.

Rheem shall be permitted to test its model GDE(-) and GLE(-) induced draft furnaces on the basis of the test procedures specified in 10 CFR part 430, with the modifications set forth below.

(i) Section 9.3.1 of ANSI/ASHRAE Standard 103-1982 is deleted and replaced with the following paragraph:

Gas- and Oil-Fueled Central Furnaces. After equilibrium conditions are achieved following the cool-down test and the required measurements performed, turn on the furnace and measure the flue gas temperature, using the thermocouple grid described above, at 0.5 and 2.5 minutes after the main burner(s) comes on. After the burner start-up, delay the blower start-up by 1.5 minutes (t-), unless: (1) The furnace employs a single motor to drive the power burner and the indoor air circulation blower, in which case the burner and blower shall be started together; (2) the furnace is designed to operate using an unvarying delay time that is other than 1.5 minutes, in which case the fan control shall be permitted to start the blower, or (3) the delay time results in the activation of a temperature safety device which shuts off the burner, in which case the fan control shall be permitted to start the blower. In the latter case, if the fan control is adjustable, set it to start the blower at the highest temperature. If the fan control is permitted to start the blower, measure the time delay, (t-), using a stopwatch. Record the measured temperatures. During the heat-up test for oil-fueled furnaces, maintain the draft in the flue pipe with ± 0.01 inch of water gauge of the manufacturer's recommended on-period draft.

This interim waiver is based upon the presumed validity of statements and all allegations submitted by the company. This interim waiver may be revoked or modified at any time upon a determination that the factual basis underlying the application is incorrect.

The interim waiver shall remain in effect until the Department of Energy issues a determination on Rheem's Petition for Waiver.

Sincerely,

J. Michael Davis,
Assistant Secretary, Conservation and Renewable Energy.

September 29, 1989.

Assistant Secretary, Conservation and Renewable Energy,
United States Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585.

Gentlemen: This is a petition for waiver and petition for interim waiver submitted pursuant to 10 CFR 430.27. Waiver is requested from the furnace test procedure found at appendix N to subpart B of part 430. The test procedure requires a 1.5 minute delay between burner on and blower on. Rheem is requesting authorization to use a 30 second delay instead of 1.5 minutes. Rheem is manufacturing a series of induced draft furnaces which include the (-)GDE upflow models and (-)GLE downflow models. Maximum energy efficiency is achieved by

fixed timing controls installed in these models that activate the circulating air blower 30 seconds after the burner is on. Under the appendix N procedures, the stack temperature is allowed to climb at a faster rate than it would be with a 30 second blower on time, allowing energy to be lost out the vent system. This waste of energy would not occur in actual operation. If this petition is granted, the true blower on time delay would be used in the calculations. Proposed ASHRAE Standard 103-1982R of 9/25/87 paragraph 9.5.1.2.2 specifically addresses the use of timed blower operation.

The current test procedures do not give Rheem credit for the energy savings which averages approximately .6 percent. This improvement is an average reduction of 3 percent of the energy loss. Rheem is of the opinion that a 3 percent reduction is a worthwhile energy savings.

Current prescribed test procedures prohibit Rheem from taking credit for the saved energy, thus providing inaccurate comparative data.

Rheem has been granted a waiver permitting the 30 second blower on time to be used in the efficiency calculations for our (-) GEB and (-)GKA series condensing furnaces. These furnaces use the same blower time control as the (-)GDE and (-)GLE series furnaces.

Several other manufacturers of condensing furnaces have been granted a waiver to permit calculations based on timed blower operation.

Confidential comparative test data is available to you upon your request, confirming the above energy savings.

Manufacturers that domestically market similar products are being sent a copy of this petition for waiver and petition for interim waiver.

Sincerely,

Daniel J. Canclini,

Vice-President, Product Development & Research Engineering.

[FR Doc. 90-2159 Filed 1-30-90; 8:45 am]

BILLING CODE 6450-01-M

Office of Fossil Energy

[ERA Docket No. 88-73-NG]

Falcon Seaboard Gas Co.; Application to Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application to import natural gas from Canada.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on December 12, 1988, of an application filed by Falcon Seaboard Gas Company (FSGC), and supplemented on August 4, and December 28, 1989, for authorization to import up to 54 MMcf per day or up to 20 Bcf of Canadian natural gas annually over a period of 15 years beginning on the date of first delivery. First delivery

of gas is expected to occur in November 1990. The imported gas would be used primarily to fuel three proposed 79-MW cogeneration plants to be located near Plattsburgh, New York. Up to 1.5 MMcf per day of the gas would be sold to the Georgia-Pacific Corporation (Georgia-Pacific). The imported gas would be transported from the U.S./Canadian border near Champlain, New York, to the cogeneration plants and Georgia-Pacific via 26 miles of 12-inch pipeline to be constructed by Falcon Seaboard Pipeline Company (FSPC), an affiliate of the applicant. An environmental assessment is being prepared by the Federal Energy Regulatory Commission (FERC) with respect to the new construction (Falcon Seaboard Pipeline Co., FERC Docket Nos. CP89-362-000 and CP89-363-000). FSGC seeks authority to import the gas from FSC Resources Limited (FSC) who, in turn, would purchase the gas from Western Gas Marketing Limited (WGML), or from substitute supplies if the gas is available at prices more competitive than WGML's.

The application if filed pursuant to section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204-111 and 0204-127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene, notices of intervention, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., e.s.t., March 2, 1990.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F-056, FE-50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Stanley C. Vass, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F-056, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-4819.

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E-042, (202) 586-6667.

SUPPLEMENTARY INFORMATION: The application was filed jointly by FSPC and FSGC but the application indicates that only FSGC will take title to the Canadian gas. Accordingly, the DOE is treating FSGC as the applicant. FSGC is an affiliate of FSPC and of the Falcon Seaboard Oil Company. The application as supplemented states that FSGC would purchase the Canadian gas from

FSC, a Canadian affiliate, who in turn would purchase the gas from WGML.

FSGC requested confidential treatment of part of the pricing provisions contained in the import arrangement. The DOE denied the request for confidential treatment in a letter to the applicant dated September 19, 1989. Subsequently, in a letter dated September 22, 1989, the applicant notified the DOE that it wished to continue to seek approval of the proposed import even with full public disclosure of the application.

Under the FSC/FSGC gas purchase agreement, the price that FSGC would pay FSC for the Canadian gas would consist of a demand charge and a commodity charge. The demand charge is the sum of the components of the monthly demand charge that FSC is required to pay WGML and the monthly demand charge of TransCanada PipeLines Limited (TransCanada) for transportation of the gas. The commodity charge that FSGC must pay FSC is the sum of the commodity charge that FSC must pay to WGML and the commodity and fuel charge FSC is required to pay to TransCanada. The commodity charge payable to WGML would be based upon the price received by WGML from local distribution companies (LDCs) in eastern Canada for gas that is resold to the LDC's "core customers," who are defined as customers using gas primarily for space and water heating and cooking.

The FSC/FSGC gas purchase contract contains no minimum take or take-or-pay provisions. The contract permits FSGC to direct FSC to purchase substitute more competitively priced gas supplies in lieu of gas from WGML to the extent that FSC can reduce its maximum daily contract quantity under FSC's gas purchase agreement with WGML. The FSC/WGML agreement permits FSC to reduce its maximum daily contract quantity if the gas supply reserves supporting WGML's supply obligations to FSC fall below certain specified levels, and at certain specified times during the first four years of the contract if FSC pays WGML certain compensation.

The applicant estimates that the price of the gas at the 100 percent load factor would be \$2.58 per MMBtu. Specifically, the demand charge that FSGC would pay to FSC for November 1989 is based on the demand charge that FSC must pay WGML and TransCanada. The demand charge which FSC must pay WGML consists of the average demand charge of NOVA Corporation of Alberta, which is estimated to be 13 cents per MMBtu for November 1989, plus a negotiated figure of 21 cents per MMBtu.

The TransCanada demand charge is estimated to be 60 cents per MMBtu. This results in a total estimated demand charge to be paid by FSGC for the imported gas for November 1989 of 94 cents per MMBtu at a 100 percent load factor.

The commodity charge that FSGC would pay FSC for November 1989, consisting of an amount equal to the sum of the commodity and fuel charges FSC would pay WGML and TransCanada, is estimated by the applicant to be \$1.64 per MMBtu of natural gas. The computation of the estimated commodity price is as follows: The price received by WGLM from eastern Canada LDC for gas resold by the LDCs to core customers for November 1989, estimated to be \$1.77 for MMBtu less the estimated demand charge paid by FSC to WGML at a 100 percent load factor of \$.34, equals \$1.43 per MMBtu. To this amount is added the estimated commodity and fuel charges paid to TransCanada of \$.09 and \$.12 respectively for a total estimated commodity charge of $\$1.43 + \$.09 + \$.12 = \1.64 per MMBtu for November 1989.

FSPC would transport the gas for FSGC from the U.S./Canadian border to three proposed cogeneration facilities and Georgia-Pacific via a 26-mile pipeline to be constructed by FSPC. The three proposed cogeneration facilities, which would also be affiliates of FSGC, Adirondack Power Inc., Saranac Energy Company, Inc., and Empire Power Company, Inc.

The electricity produced by the three facilities would be sold to the New York State Electric and Gas Corporation. The steam produced would be supplied to nearby firms. The application indicates that each of the proposed cogeneration facilities would be operated as a qualifying facility under section 201 of the Public Utilities Regulatory Policies Act of 1978.

In support of its application, FSGC asserts that the price of the gas imported would be competitive since the commodity charge is, in part, a function of the price received by WGML for gas sales to certain LDCs in eastern Canada and since FSGC can direct the exporter, FSC, to obtain substitute supplies if the substitute gas supplies are available at a more competitive price. In addition, except for the small percentage of the imported gas that would be sold to Georgia-Pacific, FSGC and its affiliates would be seller, purchaser, and end-user of the gas and thus would suffer the losses that might be incurred if the gas prices were not competitive.

The decision on FSGC's application for import authority will be made

consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Other matters that may be considered in making a public interest determination include need for gas and security of the long-term supply. Parties that may oppose this application should comment in their responses on the issues of competitiveness, need for the gas, and security of supply as set forth in the policy guidelines. The applicant asserts that this import arrangement is in the public interest because the volumes are needed to fuel three proposed new cogeneration plants, the price of the gas is competitive, and its Canadian supplier is reliable. Parties opposing the import arrangement bear the burden of overcoming these assertions.

NEPA Compliance

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) requires the DOE to give appropriate consideration to the environmental effects of its proposed actions. The FERC is currently performing an environmental review of the impacts of constructing and operating the proposed facilities related to this project. The DOE will independently review the results of the FERC environmental evaluation of this project in the course of making its own environmental determination. No final decision will be issued in this proceeding until the DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590.

Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of FSGC's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056 at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 24, 1990.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 90-2161 Filed 1-30-90; 8:45 am]

BILLING CODE 6450-01-M

[FE Docket No. 89-89-NG]

Unicorp Energy, Inc.; Application for Blanket Authorization To Export Natural Gas to Canada and Mexico

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for blanket authorization to export natural gas to Canada and Mexico.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on December 21, 1989, of a request by Unicorp Energy, Inc. (Unicorp) to amend and extend its blanket authorization to export natural gas to Canada. Unicorp, a Delaware corporation, is currently authorized by DOE/ERA Opinion and Order No. 224 (1 ERA Para. 70,843), issued February 5, 1988, and filed in ERA Docket No. 87-55-NG, to export up to 145 Bcf of natural gas to Canada for a two-year period ending March 10, 1990. Unicorp is requesting that its authorization be (1) amended to allow it to export natural gas to Mexico in addition to Canada, up to a combined total of 145 Bcf for both countries, and (2) extended for a two-year period beginning March 11, 1990, and ending March 10, 1992. The DOE intends to process Unicorp's request as a filing for a new blanket authorization to export up to a combined total of 145 Bcf of natural gas to Canada and Mexico during a two-year term beginning March 11, 1990, and ending March 10, 1992.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204-111 and 0204-127. Protests, motions to intervene, notices of intervention and written comments are invited.

DATES: Protests, motions to intervene, notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., e.s.t., March 2, 1990.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F-056, FE-50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F-094, FE-50, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-4523.

Michael T. Skinker, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-6667.

SUPPLEMENTARY INFORMATION: Unicorp is a wholly owned subsidiary of Unicorp Canada Corporation. Unicorp is a marketer of natural gas supplies, acting as agent on behalf of both producers and purchasers. If the requested authorization is granted, the company

plans to secure natural gas from a variety of supplies principally in the states of Texas, Oklahoma, and Kansas and resell the gas to spot market purchasers, including local distribution companies and commercial and industrial end-users at the Canadian and Mexican borders of the United States.

The company states that it may also purchase supplies of gas from Canada and import that gas to the U.S. under separate import authority and then export the gas back across the border to Canada. Import authority was granted in DOE/ERA Opinion and Order No. 222 (1 ERA Para. 70,754), issued January 28, 1988, filed in ERA Docket No. 87-56-NG. The price of the gas will be determined through arm's length negotiations between Unicorp and its customers with sales on a best-efforts basis. Unicorp maintains that the gas to be exported will be incremental or surplus to the needs of purchasers in areas where it is acquired.

Unicorp states that it anticipates that only existing pipeline facilities will be used for the transportation of gas to be exported and that it will submit quarterly reports giving the details of individual transactions.

This export authorization will be reviewed under section 3 of the Natural Gas Act and the authority contained in DOE Delegation Order Nos. 0204-111 and 0204-127. In deciding whether the proposed export of natural gas is in the public interest, domestic need for the gas will be considered, and any other issues determined to be appropriate, including whether the arrangement is consistent with the DOE policy of promoting competition in the natural gas marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties, especially those that may oppose this application, should comment on these matters as they relate to the requested export authority. The applicant asserts that the proposed exports would be incremental to the needs of current purchasers and the domestic gas would be exported under the proposed arrangement from those areas with sufficient natural gas production. Parties opposing this arrangement bear the burden of overcoming this assertion.

Unicorp requests expedited treatment of its application. A decision on Unicorp's request for expedited treatment will not be made until all responses to this notice have been received and evaluated.

NEPA Compliance

The DOE has determined that compliance with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, can be accomplished by means of a categorical exclusion. On March 29, 1989, the DOE published in the *Federal Register* (54 FR 12474) a notice of amendments to its guidelines for compliance with NEPA. In that notice, the DOE added to its list of categorical exclusions the approval or disapproval of an import/export authorization for natural gas in cases not involving new construction. Application of the categorical exclusion in any particular case raises a rebuttable presumption that the DOE's action is not a major Federal action under NEPA. Unless it appears during the proceeding on this application that the grant or denial of the authorization would significantly affect the quality of the human environment, the DOE expects that no additional environmental review will be required.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-

type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, a notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR § 590.316.

A copy of Unicorp's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on January 24, 1990.

Constance L. Buckley,

Deputy Assistant Secretary For Fuels Programs, Office of Fossil Energy.

[FR Doc. 90-2160 Filed 1-30-90; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3717-2]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATES: Comments must be submitted on or before March 2, 1990.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA (202) 382-2740.

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: Suspended and cancelled Pesticide Products: Claim for Indemnification. (EPA ICR # 1241.04; OMB # 2070-0071). This ICR requests renewal of an existing clearance.

Abstract: Under section 15 of the Federal Insecticide, Fungicide, Rodenticide Act, the EPA must indemnify owners of suspended and cancelled pesticide products. To accomplish this, sellers (e.g., manufacturers, dealers and distributors) and end users (e.g., farmers, householders) must submit their claims to EPA. The submission includes owner and product identifiers, and documentation of product cost, location, and ownership. Based on this information, the Agency determines the owner's right to indemnification.

Burden Statement: The public reporting burden for this collection of information is estimated to average 2.0 hours per response. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Respondents: Pesticide sellers and end users.

Estimated No. of Respondents: 1000.

Estimated Total Annual Burden on Respondents: 2000 hours.

Frequency of Collection: On occasion.

Send comments regarding the burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street, SW., Washington, DC 20460

and

Tim Hunt, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Telephone: (202) 395-3084.

Dated: January 12, 1990.

Paul Lapsley,

Information and Regulatory Systems Division.

[FR Doc. 90-2211 Filed 1-30-90; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3719-1]

Transfer of Data To Contractor

AGENCY: Environmental Protection Agency.

ACTION: Notice of transfer of data and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) will transfer to its contractor Science Applications International Corporation (SAIC) information which has been, or will be, submitted to EPA under section 3007 of the Resource Conservation and Recovery Act (RCRA). This firm is assisting EPA in developing and maintaining a data base of information submitted to EPA under the Medical Waste Demonstration Program. Some of the information may have a claim of business confidentiality.

DATES: The transfer of data submitted to EPA will occur no sooner than February 7, 1990.

ADDRESSES: Comments should be sent to Dina Villari, Information Management Specialist, Office of Solid Waste (OS-312), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460. Comments should be identified as "Transfer of Confidential Data."

FOR FURTHER INFORMATION CONTACT: Dina Villari, Information Management Specialist, Office of Solid Waste (OS-312), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460, (202) 382-4670.

SUPPLEMENTAL INFORMATION:

I. Transfer of Data

On November 1, 1988, the Medical Waste Tracking Act of 1988 (MWTAA) was enacted as an amendment to the Resource Conservation and Recovery Act (RCRA). The statute requires the Agency to establish a two-year demonstration program for the tracking and management of medical wastes, and to report to Congress on, among other issues, the generation and management of medical wastes, changes in medical waste practices resulting from federal regulations, and the success of the demonstration program. On March 24, 1989 (54 FR 12326-12395), EPA promulgated a interim final rule establishing the demonstration program.

Central to EPA efforts to collect information to be presented in the report to Congress, are the reporting requirements applicable to transporters and generators that operate incinerators on-site. Transporters of medical wastes are required to submit a one-time notification of their intent to transport regulated medical wastes, and detailed semi-annual reports describing the sources and destinations of the medical wastes they haul. Operators of on-site incinerators that burn regulated medical wastes are required to twice submit reports containing waste feed and facility information.

SAIC (EPA Contract No. 68-01-7490) will assist the Office of Solid Waste in processing these reports (i.e., "Medical Waste Transporter Semi-Annual Report" and the "On-Site Medical Waste Incinerator Report") and in operating an information management system that will store the information submitted to EPA in the above-noted reports. Some of the information being transferred may have been, or will be, claimed as confidential business information.

In accordance with 40 CFR 2.305(h), EPA has determined that SAIC requires access to confidential business information (CBI) submitted to EPA under the authority of RCRA to perform work satisfactorily under the above-noted contract. EPA is issuing this notice to inform all submitters of confidential business information that EPA may transfer to this firm, on a need-to-know basis, CBI collected under the authority of RCRA. Upon completing their review of materials submitted, the contractor will return all such materials to EPA.

SAIC has been authorized to have access to RCRA CBI under the EPA "Contractor Requirements for the Control and Security of RCRA Confidential Business Information" security manual. EPA will approve the security plan of the contractor and will inspect their facility and approve them prior to RCRA CBI being transmitted to the contractors. Personnel from this firm will be required to sign non-disclosure agreements and be briefed on appropriate security procedures before they are permitted access to confidential information, in accordance with the "RCRA Confidential Business Information Security Manual" and the Contractor Requirements Manual.

Dated: January 11, 1990.

Mary A. Gade,

Acting Assistant Administrator.

[FR Doc. 90-2212 Filed 1-30-90; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3718-8]

Relative Risk Reduction Strategies Committee; Risk Reduction Subcommittee Meeting

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given of a public meeting of the Risk Reduction Subcommittee of the Relative Risk Reduction Strategies Committee (RRRSC). The Subcommittee will meet on February 9, 1990 8:30 a.m. to 3 p.m. at the Howard Johnson's National Airport

Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202.

Purpose: The purpose of this meeting is to discuss environmental risk reduction strategies based, in part, on an evaluation of EPA's 1987 report "Unfinished Business" and to develop a methodology for developing new strategies. For further information concerning this project, please refer to the notices contained in 54 FR 35386, August 25, 1989, and 54 FR 38282, September 15, 1989.

FOR FURTHER INFORMATION: Members of the public wishing further information concerning the Subcommittee or the meeting should contact Dr. Richard Cothorn, Designated Federal Official, U.S. Environmental Protection Agency (A-101F), 401 M Street, SW., Washington, DC, (202) 382-2552 (FTS) 382-2552, FAX (202) 475-9693. Seating at the meeting is on a first come basis.

Dated: January 24, 1990.

A. Robert Flaak,

Acting Director, Science Advisory Board.

[FR Doc. 90-2213 Filed 1-30-90; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3718-9]

Science Advisory Board; Relative Risk Reduction Strategies Committee; Open Meetings

Under Public Law 92-463, notice is hereby given that the Relative Risk Reduction Strategies Committee of the Science Advisory Board will hold a series of meetings: March 27 from 10 a.m. to 5 p.m. and on March 28 from 8:30 a.m. to 3 p.m.; April 19 from 8 a.m. to 5 p.m. and on April 20 from 8:30 a.m. to 1 p.m.; May 15 from 1 p.m. to 5 p.m. and on May 16 from 8:30 a.m. to 5 p.m.; also, if needed, an additional meeting will be held on June 20 from 10 a.m. to 5 p.m. and on June 21 from 8:30 a.m. to 1 p.m. The purpose of the meeting is to discuss the progress of the three Subcommittees: Environmental Risk; Relative Risk; and Health Risk. For further information concerning this project, please refer to the notices contained in 54 FR 38282, September 15, 1989.

The meetings are open to the public. Any member of the public wishing to attend or submit written comments should notify Joanna Foellmer or Dr. Donald G. Barnes, Director, Science Advisory Board, at 202-382-4126, by one week prior to the meeting date.

Dated: January 22, 1990.
 Donald G. Barnes,
 Director, Science Advisory Board.
 [FR Doc. 90-2214 Filed 1-30-90; 8:45 am]
 BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

January 22, 1990.

The Federal Communications Commission has submitted the following information collection requirement to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act, as amended (44 U.S.C. 3501-3520).

Copies of the submission may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. Persons wishing to comment on this information collection should contact Eyvette Flynn, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-3785. Copies of these comments should also be sent to the Commission. For further information contact Jerry Cowden, Federal Communications Commission, (202) 632-7513.

OMB Number: 3060-0004.

Title: Sections 1.1307, 1.1308, 1.1311—Environmental Information Collection Requirements.

Action: Extension.

Respondents: Individuals or households, state or local governments, businesses (including small businesses), and non-profit institutions.

Frequency of Response: On occasion.

Estimated Annual Burden: 1,156 responses; 2,428 hours total annual burden; 2.1 hours average burden per response.

Needs and Uses: In fulfilling its obligation under the National Environmental Policy Act, the Commission collects environmental information from applicants whose proposals to construct or modify communications facilities may have a significant environmental impact.

Federal Communications Commission,
 Donna R. Searcy,
 Secretary.

[FR Doc. 90-2102 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

January 23, 1990.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. For further information on this submission, contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Eyvette Flynn, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-3785.

OMB Number: 3060-0046.

Title: Application for New or Modified Common Carrier Radio Station Authorization Under part 22.

Form Number: FCC Form 401.

Action: Extension.

Respondents: Businesses or other for-profit (including small businesses)

Frequency of Response: On occasion.

Estimated Annual Burden: 16,500

Responses; 132,000 Hours.

Needs and Uses: The FCC Form 401 is used by common carrier applicants (telephone companies, radio and other miscellaneous carriers) to request authority to construct a radio station. Such filings are required by law under the provisions of the Communications Act and FCC Rules part 22 to determine the technical, legal and other qualifications of the applicant to operate the station. Without this information the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

Donna R. Searcy,
 Secretary.

[FR Doc. 90-2103 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

January 25, 1990.

The following information collection requirements have been approved by the Office of Management and Budget as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). For further information contact Judy Boley, Federal

Communications Commission, (202) 632-7513.

OMB No.: 3060-0003.

Title: Application for Amateur Radio Station and/or Operator License.

Form No.: FCC 610.

A revised application form FCC 610 has been approved for use through 12/13/92. The September 1987 edition with an OMB expiration date of 12/13/89 will remain in use until updated forms are available.

OMB No.: 3060-0028.

Title: Application for Authorization in the Auxiliary Radio Broadcast Services.

Form No.: FCC 313.

A revised application from FCC 313 has been approved for use through 10/31/92. The current edition of the form is dated November 1989 and is now available. The April 1987 edition with an OMB expiration date of 10/31/89 will be accepted by the Commission until April 30, 1990.

OMB No.: 3060-0064.

Title: Application for Station Authorization in the Private Operational Fixed Microwave Radio Service.

Form No.: FCC 402.

The approval on FCC 402 has been extended through 10/13/92. The current edition of the form is dated December 1989. The previous editions with an OMB expiration date of 10/31/89 will remain in use until the revised form are available.

OMB No.: 3060-0065.

Title: Application for New or Modified Radio Station Authorization Under part 5 of FCC Rules—Experimental Radio Service (Other Than Broadcast).

Form No.: FCC 442.

The approval on FCC 442 has been extended through 12/31/92. The February 1987 edition with the previous expiration date of 12/31/89 will remain in use until updated forms are available.

Federal Communications Commission.

Donna R. Searcy,
 Secretary.

[FR Doc. 90-2104 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

January 24, 1990.

The Federal Communications Commission has submitted the following information collection requirements to the Office of Management and Budget for review and clearance under the

Paperwork Reduction Act, as amended (44 U.S.C. 3501-3520).

Copies of the submissions may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. Persons wishing to comment on these information collections should contact Eyvette Flynn, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-3785. Copies of these comments should also be sent to the Commission. For further information contact Jerry Cowden, Federal Communications Commission, (202) 632-7513.

OMB Number: 3060-0303

Title: Section 97.5, Station license required

Action: Extension

Respondents: Individuals or households
Frequency of Response: Recordkeeping requirement

Estimated Annual Burden: 40,000 recordkeepers; 40 hours total annual burden; 3 seconds average burden per recordkeeper

Needs and Uses: Rule is needed to assure that amateur radio stations are licensed in conformance with the Communications Act of 1934, as amended, as well as the International Telecommunications Union Radio Regulations.

OMB Number: 3060-0323

Title: Section 97.527, Reimbursement for expenses

Action: Extension

Respondents: Individuals or households and non-profit institutions

Frequency of Response: Recordkeeping requirement and annual reporting

Estimated Annual Burden: 3,500

responses; 3,500 recordkeepers; 42,585 hours total annual burden; 6 hours average burden per response or recordkeeper

Needs and Uses: Rule is needed to assure that volunteer examiner coordinators and volunteer examiners do not collect reimbursement for other than necessary and prudent expenses.

OMB Number: 3060-0302

Title: Section 97.9, Operator license

Action: Extension

Respondents: Individuals or households
Frequency of Response: Recordkeeping requirement

Estimated Annual Burden: 40,000 recordkeepers; 40 hours total annual burden; 3 seconds average burden per recordkeeper

Needs and Uses: Rule is needed to assure that amateur radio operators are licensed in conformance with the Communications Act of 1934, as amended, as well as the International Telecommunications Union Radio Regulations.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2105 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

FCC Establishes Advisory Committee for the 1992 World Administrative Radio Conference (92-WARCAC)

January 24, 1990.

The Federal Communications Commission has established an Advisory Committee for the World

Administrative Radio Conference for Dealing with Frequency Allocations in Certain Parts of the Spectrum (92-WARCAC). This committee is being organized to advise the FCC Staff concerning preparations for the conference. The committee will develop and present recommendations for U.S. proposals and positions concerning topics to be addressed at the Conference.

In order to assure that a fairly balanced membership is attained on the committee, the FCC will carefully select prominent and knowledgeable individuals from business, industry and other arenas. The members will be chosen so that the largest possible diversity of interests will be represented. The formation of the Advisory Committee is necessary and in the public interest since the FCC is seeking as much outside input as possible before establishing positions for the conference.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90-2101 Filed 1-30-90; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; Kelly Broadcasting Corp.

1. The Commission has before it the following mutually exclusive applications for renewal of license of Station WNIK-FM, Arecibo, Puerto Rico, and for a New FM Station at Arecibo, Puerto Rico:

Applicant	City/state	File No.	MM Docket No.
A. Kelly Broadcasting Corporation (WNIC-FM)	Arecibo, Puerto Rico	BRH-881014RF	89-627
B. San Luis Broadcasting, Inc.	Arecibo, Puerto Rico	BPH-890103MC	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each issue has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name above is used below to signify whether the issue in question applies to that particular applicant.

Issue heading	Applicant(s)
1. Financial	B
2. Comparative	A, B
3. Ultimate	A, B

3. If there is any nonstandardized issue in this proceeding, the full text of the issue and the applicants to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets

Branch (Room 230), 1919 M Street, NW., Washington, DC 20554. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037. (Telephone (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division,
Mass Media Bureau.

[FR Doc. 90-2100 Filed 1-30-90; 8:45 a.m.]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION**Israel Eastbound Conference Agreement and U.S./Central American Liner Association; Agreements Filed**

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-010790-008.

Title: Israel Eastbound Conference Agreement.

Parties: Zim Israel Navigation Co., Ltd., Farrell Lines, Inc., Lykes Bros. Steamship Company, Inc.

Synopsis: The proposed amendment would expand the geographic scope of the Agreement to include cargo shipped from ports and points in the states of Hawaii and Alaska.

Agreement No.: 202-010987-010.

Title: United States/Central America Liner Association.

Parties: Crowley Caribbean Transport, Inc., Seaboard Marine, Ltd., Crowley Trailer Marine Transport, Inc., Sea-Land Service, Inc.

Synopsis: The proposed modification would republish the basic Agreement and would add provisions for voting sections and confidentiality.

By Order of the Federal Maritime Commission.

Dated: January 26, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-2219 Filed 1-30-90; 8:45 am]

BILLING CODE 6730-01-M

Port Everglades Authority/Crowley Caribbean Transports and Georgia Ports Authority/Hanjin Terminal; Agreements Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10220. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-200318

Title: Port Everglades Authority/Crowley Caribbean Transport, Inc. Terminal Agreement.

Parties: Port Everglades Authority (PEA), Crowley Caribbean Transport, Inc. (Crowley).

Synopsis: The Agreement provides for PEA's 10-year lease to Crowley of approximately 55 acres at Southport, Port Everglades, Florida for use as a container/RoRo terminal including the storage of containers, related equipment and cargo as well as for partial use as a container freight station. The basic annual rent for the leased land is \$800.00 per acre per month plus sales tax. Additional rent for 1,000 square feet of administration space is \$5.00 per square foot per year plus sales tax. The Agreement also provides for future rent adjustments, Crowley's payment of a minimum wharfage charge based on 550,000 tons per year plus 10,000 additional tons for each additional acre leased, Crowley's preferential berthing at Berths 33A, 33B, and 33C at Southport, and the assessment of certain dockage charges against Crowley.

Agreement No.: 224-010880-003

Title: Georgia Ports Authority/Hanjin Terminal Agreement.

Parties: Georgia Ports Authority, Hanjin Container Lines, Ltd.

Synopsis: The Agreement modifies the rate schedule of Agreement No. 224-010880 to provide for a decrease in the consolidated rate for terminal services from \$95.10 per container to \$94.55 per container and the unloaded empty container rate from \$24.98 per container to \$24.84 per container, effective January 19, 1990.

By the Federal Maritime Commission.

Dated: January 25, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-2135 Filed 1-30-90; 8:45 am]

BILLING CODE 6730-01-M

Tampa Port Authority/Tampa Bay International Terminal; Agreement(s) Filed

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10220. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments and protests are found in § 560.602 and/or § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 224-200317

Title: Tampa Port Authority/Tampa Bay International Terminals Terminal Agreement.

Parties: Tampa Port Authority (Authority), Tampa Bay International Terminals (TBIT).

Filing party: Mr. H. E. Welch, Director of Traffic, Tampa Port Authority, P.O. Box 2192, 811 Wynkoop Road, Tampa, FL 33601.

Synopsis: The Agreement provides that TBIT will operate general cargo marine terminal facilities under the control of the Authority. The Agreement will take the place of lease Agreements Nos. 224-200057 and 224-010877 for specific terminal facilities as the lease agreements expire, supplanting such lease provisions as minimum financial guarantee, responsibilities for maintenance, and other obligations.

By Order of the Federal Maritime Commission.

Dated: January 25, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-2134 Filed 1-30-90; 8:45 am]

BILLING CODE 6730-01-M

**Issuance of Certificates [Casualty];
Epirotiki Lines, Inc. et al.**

In the matter of security for the protection of the public financial responsibility to meet liability incurred for death or injury to passengers or other persons on voyages.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of section 2, Public Law 89-777 (80 Stat. 1356, 1357) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540):

Epirotiki Lines, Inc. and Hellenic Co.,
Overseas Cruise Vessels, S.A., 551
Fifth Avenue, New York, New York
10176

Vessel: World Renaissance

Dated: January 25, 1990.

Joseph C. Polking,

Secretary.

[FR Doc. 90-2095 Filed 1-30-90; 8:45 am]

BILLING CODE 6730-01-M

**Notice of Issuance of Certificate
(Performance)**

In the matter of security for the protection of the public indemnification of passengers for nonperformance of transportation.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR part 540):

Epirotiki Lines Inc. and Hellenic Co.,
Overseas Cruise Vessels, S.A., 551
Fifth Avenue, New York, New York
10176

Vessel: World Renaissance

Dated: January 25, 1990.

Joseph C. Polking,

Secretary.

[FR Doc. 90-2096 Filed 1-30-90; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM**The Daiwa Bank, Ltd., et al.; Notice of
Applications To Engage de novo in
Permissible Nonbanking Activities**

The companies listed in this notice have applied under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval

under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 20, 1990.

A. Federal Reserve Bank of New York
(William L. Rutledge, Vice President) 33
Liberty Street, New York, New York
10045:

1. *The Daiwa Bank, Ltd.*, Osaka, Japan; to engage *de novo* through its subsidiary, Daiwa Bk (Connecticut) Inc., Hartford, Connecticut, in soliciting and developing opportunities for making commercial loans, commercial real estate loans, and other extensions of credit pursuant to § 225.25(b)(1) of the Board's Regulation Y. Subsidiary itself will not make any loans or extend any form of credit. These activities will be conducted in Connecticut and geographic areas proximate thereto.

B. Federal Reserve Bank of Chicago
(David S. Epstein, Vice President) 230
South LaSalle Street, Chicago, Illinois
60690:

1. *Hasten Bancorp, Indianapolis, Indiana*; to engage *de novo* through its

subsidiary, Hasten Financial Services, Inc., in securities brokerage activities pursuant to § 225.25(b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 25, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-2148 Filed 1-30-90; 8:45 am]

BILLING CODE 6210-01-M

**Eagle Bancorp, Inc., et al.; Formation
of, Acquisition by, or Merger of Bank
Holding Companies**

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than February 20, 1990.

A. Federal Reserve Bank of Atlanta
(Robert H. Heck, Vice President) 100
Marietta Street, NW., Atlanta, Georgia
30303:

1. *Eagle Bancorp, Inc.*, Statesboro, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Eagle Bank and Trust, Statesboro, Georgia.

Board of Governors of the Federal Reserve System, January 25, 1990.

Jennifer J. Johnson,

Associated Secretary of the Board.

[FR Doc. 90-2149 Filed 1-30-90; 8:45 am]

BILLING CODE 6210-01-M

**Security Bank Holding Company
Employee Stock Ownership Plan;
Change in Bank Control Notice;
Acquisition of Shares of Banks or
Bank Holding Companies**

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 14, 1990.

A. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President), 101 Market Street, San Francisco, California 94105:

1. *Security Bank Holding Company Employee Stock Ownership Plan*, Coos Bay, Oregon; to acquire an additional 7.4 percent of the voting shares of Security Bank Holding Company, Coos Bay, Oregon, and thereby indirectly acquire Security Bank, Coos Bay, Oregon.

Board of Governors of the Federal Reserve System, January 25, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-2150 Filed 1-30-90; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

[File No. 861 0118]

**The Reading Hospital, et al.; Proposed
Consent Agreement With Analysis To
Aid Public Comment**

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of Federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, the Berks County, Pa. hospitals from acquiring, without prior Commission approval, all or part of any hospital in Berks County, Pa. Respondents would also be prohibited from transferring any hospital they

operate in Berks County to a person that operates or is acquiring a hospital in Berks County, without prior Commission approval.

DATES: Comments must be received on or before April 2, 1990.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Mark Horoschak, FTC/S-3115, Washington, DC 20580. (202) 326-2756.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

**The Reading Hospital and Community
General Hospital; Agreement Containing
Consent Order**

The Federal Trade Commission, having initiated an investigation into the consolidation of The Reading Hospital ("Reading Hospital") and Community General Hospital ("Community General") through the formation of Berkshire Health System ("BHS"), and it now appearing that Reading Hospital and Community General, hereinafter sometimes referred to as proposed respondents, are willing to enter into an agreement containing an order to cease and desist;

It is hereby agreed by and between Reading Hospital and Community General, by their duly authorized officers and attorneys, and counsel for the Federal Trade Commission that:

1. Proposed respondent Reading Hospital is a corporation organized, existing and doing business under and by virtue of the laws of the State of Pennsylvania, with its office, principal place of business and mailing address at Sixth Avenue and Spruce Street, Reading, Pennsylvania 19603. Proposed respondent Community General is a corporation organized, existing and doing business under and by virtue of the laws of the State of Pennsylvania, with its office and principal place of business in Reading, Pennsylvania, and

its mailing address at P.O. Box 1728, Reading, Pennsylvania 19603.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft of complaint here attached.

3. Proposed respondents waive:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

(d) Any claim under the Equal Access to Justice Act.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so ordered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondents' addresses as stated in this

agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the proposed complaint and order contemplated hereby. They understand that once the order has been issued, they may be required to file one or more compliance reports showing that they have fully complied with the order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I.

For the purposes of this order:

A. "Reading Hospital" means The Reading Hospital (a Pennsylvania corporation), its directors, trustees, officers, agents, employees, and representatives, its parents and affiliates, and its subsidiaries, divisions, successors, and assigns.

B. "Community General" means Community General Hospital (a Pennsylvania corporation), which operates a hospital of the same name in Reading, Pennsylvania, its directors, trustees, officers, agents, employees, and representatives, its parents and affiliates, and its subsidiaries, divisions, successors, and assigns.

C. "Respondents" means Reading Hospital and Community General, collectively and individually.

D. "General acute care hospital," herein referred to as "hospital," means a health facility, other than a federally owned facility, having a duly organized governing body with overall administrative and professional responsibility, and an organized medical staff, that provides 24-hour inpatient care, as well as outpatient services, and having as a primary function the provision of inpatient services for medical diagnosis, treatment, and care of physically injured or sick persons with short-term or episodic health problems of infirmities.

E. To "acquire a hospital" means to directly or indirectly acquire all or any part of the stock or assets of any hospital, or enter into any arrangement to obtain direct or indirect ownership, management or control of any hospital or any part thereof, such as a lease of or management contract for a hospital, or

the acquisition of the right to designate directly or indirectly the directors of a hospital corporation.

F. To "operate a hospital" means to own, lease, manage, or otherwise control or direct the operations of a hospital, directly or indirectly.

G. "Affiliate" means any entity whose management and policies are controlled or directed in any way, directly or indirectly, by the person with which it is affiliated.

H. "Person" means any natural person, partnership, corporation, company, association, trust, joint venture or other business or legal entity, including any governmental agency.

II.

It is ordered That, for a period of ten (10) years from the date this order becomes final, no respondent shall, without the prior approval of the Federal Trade Commission:

A. Acquire any hospital in Berks County, Pennsylvania; or

B. Permit any hospital it operates in Berks County to be acquired by any person that operates, or is in the process of acquiring, any other hospital in Berks County.

Provided, however, that no acquisition shall be subject to this Paragraph II of this order if the fair market value of (or, in case of a purchase acquisition, the consideration to be paid for) the hospital or part thereof to be acquired does not exceed one million dollars (\$1,000,000).

III.

It is further ordered That, for a period of ten (10) years from the date this order becomes final, no respondent shall, without the prior approval of the Federal Trade Commission, permit any hospital it operates in Berks County,

Pennsylvania to be acquired by any person other than another respondent unless the respondent requires, as a condition precedent to the acquisition, that the acquiring party file with the Commission, prior to the closing of the acquisition, a written agreement to be bound by the provisions of this order.

IV.

It is further ordered, That respondents, upon written request of the Secretary of the Federal Trade Commission or the Director of the Bureau of Competition of the Federal Trade Commission made to them at their principal offices, for the purpose of securing compliance with this order, and for no other purpose, and subject to any legally recognized privilege, shall permit duly authorized representatives of the Federal Trade Commission or the Director of the Bureau of Competition:

1. Reasonable access during their office hours, in the presence of counsel, to those books, ledgers, accounts, correspondence, memoranda, reports, and other records and documents in their possession or control that relate materially and substantially to any matter contained in this order; and

2. An opportunity, subject to their reasonable convenience, to interview their officers or employees, who may have counsel present, regarding such matters.

V.

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to any proposed change, such as dissolution, assignment, sale resulting in the emergence of a successor corporation or association, or the creation or dissolution of subsidiaries or affiliates, which may affect compliance obligations arising out of this order.

The Reading Hospital and Community General Hospital Analysis To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, identical agreements to a proposed consent order from The Reading Hospital ("Reading Hospital") and Community General Hospital ("Community General"), both of Reading, Pennsylvania. The agreements would settle charges by the Federal Trade Commission that Reading Hospital and Community General violated section 7 of the Clayton Act by their consolidation through the formation of Berkshire Health System ("BHS").

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements or issue and serve the agreements' proposed order.

The Proposed Complaint

A complaint has been prepared for issuance by the Commission along with the proposed order. It alleges that in December 1985, Reading Hospital and Community General formed, and then placed themselves under the control of, BHS. All three firms are nonprofit corporations. Before this consolidation, Reading Hospital and Community General were independent competitors,

and there was only one other competitor in the market for general acute care hospital services in Berks County, Pennsylvania, according to the complaint. The consolidation allegedly made the market highly concentrated, raising BHS' market share to over 75%. The market also is difficult for new competitors to enter, according to the complaint. The complaint charges that until the consolidation was rescinded (as described below), its effect may have been to substantially lessen competition in the Berks County hospital market, in violation of section 7 of the Clayton Act.

According to the complaint, on January 18, 1989 Reading Hospital and Community General agreed to rescind their consolidation. BHS relinquished its control of Community General in late March 1989. Soon thereafter, Community General's representation on the BHS board of directors was terminated. BHS was subsequently dissolved in December 1989. As a result, Reading Hospital and Community General are once more independent competitors in the Berks County hospital market.

The Proposed Consent Order

The first paragraph of the proposed order defines the respondents subject to the order, and certain other terms used in the order. Paragraph II would prohibit respondents from acquiring, directly or indirectly, without the prior approval of the Federal Trade Commission, all or part of any hospital in Berks County, Pennsylvania. It would also prohibit respondents from transferring any hospital they operate in Berks County to a person that operates or is acquiring a hospital in Berks County. The coverage of paragraph II would be limited to acquisitions of hospitals or their assets where the purchase price, or fair market value in the case of non-purchase acquisitions (such as leases or management contracts), is more than \$1,000,000. Paragraph II would expire ten years after the order becomes final.

Paragraph III of the proposed order would prohibit, for ten years, respondents from transferring any of their hospitals in Berks County to a non-respondent without first filing with the Commission an agreement by the transferee to be bound by the order (including the requirements of Paragraph III), or obtaining prior approval from the Federal Trade Commission for not requiring such an agreement. Paragraphs II and III, in combination, would give the Commission authority to prohibit transactions combining the general acute care hospital operations of Reading Hospital and Community General, or of one of those firms and

any other general acute care hospital in Berks County, unless the parties convinced the Commission that a particular transaction would not endanger competition in the Berks County hospital market.

Paragraph IV of the proposed order requires respondents to make certain documents and personnel available to the Federal Trade Commission upon written request for the purpose of verifying compliance with the order. Paragraph V of the proposed order requires respondents to notify the Commission at least thirty days before any proposed change in corporate structure that may affect compliance with the order.

The proposed order does not require divestiture. According to the complaint, the affiliation of Community General with BHS and Reading Hospital has ended, and Community General is once again an independent competitor. Community General has settled all outstanding financial obligations resulting from its affiliation with BHS and Reading Hospital. Community General has arranged participation in its own right in a group supply purchasing agreement to which it had access as a BHS affiliate. It has also elected to continue purchasing biomedical equipment maintenance, laboratory and laundry services from Reading Hospital (but is transferring its data processing work from Reading Hospital to a non-hospital vendor), and both Community General and Reading Hospital continue as member hospitals of Berkshire Health Plan, a hospital-sponsored preferred provider organization. Otherwise, the two hospitals now operate independently of each other. The Commission has concluded that Community General is a viable, independent competitor, and that no relief beyond that contained in the proposed order is needed to restore Community General and the Berks County hospital market to their approximate pre-affiliation competitive positions.

The purpose of this analysis is to invite public comment concerning the proposed order, to assist the Commission in its determination whether to make the order final. This analysis is not intended to constitute an official interpretation of the agreements and the proposed order or to modify their terms in any way.

The agreements are for settlement purposes only and do not constitute admissions by Reading Hospital or Community General that the law has

been violated as alleged in the proposed complaint.

Donald S. Clark,

Secretary.

[FR Doc. 90-2147 Filed 1-30-90; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N-0140]

RIN 0905-AC48

Juice and Diluted Juice Beverages; Common or Usual Name for Nonstandardized Foods

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition from the National Food Processors Association (NFPA) requesting that the agency initiate rulemaking to replace the common or usual name regulation for diluted fruit or vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33) with a new regulation. The new regulation that NFPA has suggested would require, among other things, that the percentage of juice contained in a juice or diluted juice beverage be declared on the information panel, if one is present, rather than on the principal display panel. FDA is requesting that interested persons comment on this petition. FDA is also requesting comments on how to accurately represent the contents of juice blend products and diluted juice blend products containing one or more characterizing flavors, and comments on the general issue of the common or usual name regulation for diluted juice beverages (§ 102.33), including naming diluted juice beverages containing modified juices. FDA will consider all of the comments that it receives, as well as previously submitted comments and the NFPA petition, in devising its next action regarding the diluted juice beverage regulation (§ 102.33).

DATES: Written comments by April 2, 1990.

ADDRESSES: Written comments on this citizens petition or any other related matter are to be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, Fishers Lane, Rockville, Md 20857.

FOR FURTHER INFORMATION CONTACT: Terry C. Troxell, Center for Food Safety

and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 10, 1980 (45 FR 39247), FDA published a final rule establishing the common or usual name for diluted fruit or vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33), to be effective July 1, 1981. The regulation would have required that all diluted juice beverages other than diluted orange juice beverages be labeled with a descriptive name identifying the beverage and with a percentage declaration of the amount of juice contained in the beverage.

FDA extended the effective date of the regulation on three occasions, the most recent being June 27, 1984 (49 FR 26541), when the agency extended the effective date indefinitely. Just before the indefinite extension, in the Federal Register of June 1, 1984 (49 FR 22831), FDA proposed to amend 21 CFR 102.33 to: (1) Exempt cranberry juice products from the requirement that the percentage of juice in diluted juice beverages be declared on the label; (2) allow the manufacturers of other diluted high-acid juice beverages to petition for a similar exemption; (3) eliminate the requirement that the percentage of individual juices in diluted multiple-judge beverages be declared on the label; and (4) permit declaration of the percentage of juice in a product as a whole number not greater than the actual percentage contained in the beverage rather than in 5 percent increments. In the Federal Register of July 16, 1987 (52 FR 26690), FDA withdrew the June 1, 1984, proposal and proposed to revoke this common or usual name regulation (21 CFR 102.33).

II. NFPA Petition

FDA has now received a citizen petition from NFPA dated January 19, 1989 (Docket No. 80N-0140, initially assigned Docket No. 89P-0025/CP), requesting that the agency revoke the current common or usual name regulation for diluted fruit or vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33) and initiate the appropriate action to provide for a new § 102.33.

The replacement regulation that NFPA is proposing is entitled, "Common or Usual Name Regulation for Juices and Diluted Fruit or Vegetable Juice Beverages other than those that conform to a standard of identity or a separate common or usual name regulation." It states:

(a) § 102.33(a). The common or usual name of a noncarbonated beverage containing more than zero percent fruit or vegetable juice(s) (other than a juice or beverage that conforms to a definition and standard of identity or to a separate common or usual name regulation) shall be a descriptive name meeting the requirements of § 102.5(a) (e.g., "apple juice", "diluted grape juice beverage", "grape juice drink", or another descriptive phrase).

(b) The percentage of total juice contained in the product shall be declared by the words "containing (or contains) _____ percent (or percent) _____ juice" or "_____ percent (or percent) _____ juice", with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice and the second blank filled in with "fruit" or "vegetable" or with the name of the particular fruit or vegetable if the product contains only one juice. Such statement shall be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the height of the required declaration of net quantity of contents on the label, and in lines generally parallel to the base on which the package rests.

(1) If the package has an information panel as defined in § 101.2, the statement of the percent of total juice content shall appear near the top of the information panel, with no other printed label information appearing above the statement.

(2) If the package has only a principal display panel and does not have an information panel, the statement of percent of total juice content shall appear prominently and conspicuously on the principal display panel.

(c) The percent of fruit or vegetable juice(s) in a diluted juice beverage shall be calculated on the basis of the soluble solids content of the single-strength (undiluted) juice(s) used to prepare the diluted beverage and shall be declared on a volume/volume basis. If the finished beverage is prepared from concentrated juice(s), the percent of fruit or vegetable juice(s) shall be calculated on the basis of soluble solids content of the single-strength (unconcentrated) juice(s) used to produce such concentrated juice(s). The soluble solids content of single-strength high-acid juice (lemon, lime, or cranberry juice) shall be the weight of soluble solids obtained from refractometer readings corrected for acidity as set forth in § 22.025, Official Methods of Analysis of the Association of Official Analytical Chemists, 14th Ed. (1984), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists (new address: Suite 400-BW, 2200 Wilson Boulevard, Arlington, VA 22201-3301) or available for inspection at the office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

NFPA also requested that FDA withdraw the proposal that was published in the Federal Register of June 1, 1984 (49 FR 22831). The agency points out that, as discussed above, it did so in the Federal Register of July 16, 1987 (52 FR 26690).

The NFPA proposal differs from the current 21 CFR 102.33 in several respects. First, NFPA would require that the declaration of the percentage of juice contained in a produce be placed prominently on the information panel (or, in the absence of an information panel, prominently on the principal display panel) rather than as part of the statement of identity on the principal display panel (21 CFR 102.33(a)). NFPA would require that this declaration be made on the label of juices as well as on the label of diluted juice beverages. Secondly, NFPA would only require the declaration of the total percentage of juice in a multiple juice beverage. It would not require, as current § 102.33(a)(2)(ii) (21 CFR 102.33(a)(2)(ii)) does, a declaration of the percentage of individual juices in beverages that contain multiple juices but that have a label or labeling that makes representations, either directly or indirectly, about the characterizing juice. Finally, NFPA would require that the percentage of juice contained in a product be expressed as a whole number that is not greater than the actual percentage rather than in 5 percent increments, as is required in the current regulation (21 CFR 102.33(a)(2)). NFPA did not suggest changing the method of determining the percentage of juice in diluted juice beverages.

NFPA stated that its petition was the work of a special NFPA task force that NFPA convened to develop a consensus that would both receive general support from the various segments of the juice industry and provide useful, nonconfusing information in the labeling of these products to the consuming public.

In conjunction with this petition, the NFPA task force concluded that the products described in the petition should bear nutrition labeling that would allow consumers to "evaluate all products not only on the basis of taste, refreshment and juice content, but also on the basis of the contribution they make to nutrition." Consequently, the task force concluded that NFPA should initiate proposals in Congress for an amendment to the Federal Food, Drug, and Cosmetic Act (the act) that would authorize FDA to require nutrition labeling for this category of food products. The two prongs of this approach are being pursued independently of each other by NFPA.

FDA has received two substantive comments on the NFPA petition. The Coalition of Responsible Juice Companies (CRJC) requests that FDA set an effective date as soon as possible for 21 CFR 102.33, and that diluted juice

beverages bear a principal display panel disclosure of the percentage of total juice, with no exemptions for any juice. CRJC points out that FDA could alter the regulation later, if warranted, in response to public comment on the NFPA petition.

The Center for Science in the Public Interest (CSPI) states that FDA should require percentage declaration on diluted juices as soon as possible and believes that the percentage declaration should be on the principal display panel. However, the comment states, if FDA chooses to require such disclosure on the information panel, FDA should insure that the disclosure is highly visible. In addition, CSPI believes that if the information panel is designated, manufacturers should be given the option to make the percentage disclosure on the principal display panel.

These comments will be considered as part of FDA's rulemaking. They are available for review in the Dockets Management Branch (address above) under Docket No. 80N-0140.

III. Characterizing Flavor of Blended Juice Products

FDA is also concerned about accurately representing the contents of multiple juice products and diluted multiple juice products that contain minor amounts of the characterizing juice (that is, the juice that imparts a dominant or distinguishing flavor to the product), whether or not the characterizing juice has been enhanced with added flavoring. This issue is especially important if the declaration of the percentage of the juice in a product is moved from the principal display panel to the information panel and only the total percentage of juice is declared. The primary concern is to accurately represent the contents of the product while not providing misleading information to the consumer. For example, a label would be misleading if it implied that the characterizing juice is either the only juice or the major juice present in the product when it is not.

Different approaches have been suggested by NFPA, FDA, and others as to how to accurately name diluted multiple juice products that contain minor amounts of the characterizing juice. One option includes the following elements: (1) Naming the product with the name of the characterizing juice or flavor regardless of whether that juice is present in the greatest amount; (2) using the word "blended" or "blend" of juices; and (3) not using the word "flavored," even though the product may be enhanced with natural flavor derived from the characterizing juice, unless the

declared juice alone would not be the characterizing juice. Based on this option, a firm might consider it appropriate, for example, to label a grape/pear/raspberry juice blend that contains a minor amount of raspberry juice, but enough to impart a raspberry flavor to the juice, as "raspberry—a blend of three juices" or "raspberry juice blend." A similar product to which a natural raspberry flavor is added could be labeled the same way. Other labeling options include adding the word "flavored" to the name of such a product, e.g., "raspberry-flavored juice blend;" requiring as a product name "(name of characterizing juice) juice in a (blend, mixture, or base) of (number) other fruit juices," e.g., "Raspberry juice in a blend of two other fruit juices;" or requiring that all juices in the mixture be listed, either in an order of predominance (most present) or prominence (most apparent by taste).

The question also arises as to how to properly use vignettes that depict, usually in pictures, the fruits in a diluted multiple juice product with a characterizing juice. At issue here is whether to depict the fruits in such products by showing more of the fruit that is most apparent in taste (prominence) or that is present in the greatest quantity (predominance).

FDA is seeking comments on how to accurately represent, through identity statements and vignettes, diluted juice blend products with one or more characterizing juices (with or without noncharacterizing juices). The comments should address the consistency of the suggested labeling approaches with: (1) The labeling provisions of the act; (2) the regulations governing the common or usual name for nonstandardized foods (21 CFR 102.5); (3) the flavor labeling regulations found in 21 CFR 101.22(i); (4) the common or usual name for diluted fruit or vegetable juices found in 21 CFR 102.33 (effective date extended indefinitely); and (5) any other pertinent regulations.

IV. Modified Juices

Because diluted fruit and vegetable juices are sometimes made with modified juices, FDA believes that modified juices should be included among the matters considered in this proceeding. FDA has been concerned for the last several years about modified juices, including decharacterized or stripped juices. The modifications in these juices range from relatively minor changes, such as altering the acidity to improve the taste, to major modifications that remove virtually all flavors and colors, and resulting essentially in sugar water. At issue is

how a juice that has been altered by a treatment (e.g., ion exchange) that removes or replaces the constituents (such as flavors, colors, and acids) by which consumers recognize the original juice should be identified on the label.

If a modified juice is represented as the unmodified juice or is used as a component in a juice product as though it were the unmodified juice, it may result in economic deception of the consumer. For example, consumers would be economically deceived if deflavored, decolored, acid-reduced grape juice was used in a product, such as raspberry-flavored juice beverage, that was labeled with respect to the percentage of juice and to ingredient content as though the decharacterized grape juice was an unaltered juice.

FDA also is concerned that in modifying these juices, important components of the juice, such as potassium, are stripped from the juice, and other, undesirable, substances, like sodium, are added. As a result, an individual who has been advised by his physician to drink a particular juice because of its high potassium content, or who has been advised to avoid sodium, may receive something other than what he or she expects when consuming modified juices represented as ordinary juices.

The use of modified juices thus raises at least two issues. First, to be informative to consumers, to comply with the labeling provisions of section 403 of the act (21 U.S.C. 349), and to not violate the economic adulteration provisions of section 402(b) of the act (21 U.S.C. 342(b)), a modified juice product, whether sold as a single component beverage or as an ingredient in a multicomponent beverage, must be properly named. In the past, FDA has considered names such as "Acid-Reduced Apple Juice" or "Decolored, Deflavored, Acid-Reduced Grape Juice" to be appropriately descriptive names. However, names that end with the word "juice" may be misleading to consumers, who have come to associate the term "juice" with the unmodified expressed juice of a fruit or vegetable and to associate names such as "juice beverage" and "juice drink" with a product that is something less than the unmodified expressed juice of a fruit or vegetable. FDA is asking for comments on how modified juice products should be labeled so as not to deceive consumers.

Secondly, the agency has in the past expressed the opinion that these modified juice products should not be included as juices in determining the total percentage of juice in a diluted

juice beverage because they are no longer the unaltered liquid of the source fruit or vegetable. FDA is asking for comments on this view. Comments should consider whether any modification of a juice would be so minor that the modified juice may be considered a juice for calculating the juice percentage in a diluted juice beverage. Comments should address methods for FDA enforcement of any approach suggested that permits juice with minor modifications to be included when calculating the percentage of juice in a diluted juice beverage.

V. Agency Options

Because of the unresolved issues regarding naming diluted juice beverages, including the proposed revocation of 21 CFR 102.33, the agency has concluded that it would be in the best interest of all concerned to request comments on the entire issue of the common or usual name regulation for diluted juice beverages (§ 102.33) before FDA begins its review of the NFPA petition or takes any other action on this common or usual name regulation. Therefore, in accordance with 21 CFR 10.30(h)(3), FDA is requesting that all interested persons comment on any aspect of the common or usual name regulation for diluted juice beverages (§ 102.33), including the final rule of June 10, 1980 (45 FR 39247), establishing § 102.33; the proposal of July 16, 1987 (52 FR 26690), to revoke § 102.33; the NFPA petition; juice blend products and diluted juice blend products containing one or more characterizing juices; modified juices; the other considerations discussed in this notice; and any economic impact on affected parties. FDA requests that all comments submitted reference Docket No. 80N-0140.

In determining its next action on the common or usual name regulation for diluted juice beverages other than diluted orange juice beverages, the agency will consider the comments received on this notice and on relevant previous notices. Based on its evaluation of these comments, the agency may: (1) Propose a new effective date for § 102.33; (2) propose a new effective date for parts of § 102.33 and propose revisions for the other parts of that regulation; (3) propose to replace § 102.33 with NFPA's suggested regulation or a modification thereof; (4) propose to replace § 102.33 with a labeling regulation that is substantially different from both the existing § 102.33 and NFPA's suggested regulation; or (5) revoke § 102.33.

The agency encourages interested persons to obtain copies of the NFPA

petition to facilitate review and comment. Any request for a copy of the petition should be submitted in writing to the Freedom of Information Staff (HFR-35), Food and Drug Administration, RM. 12A-16, 5600 Fishers Lane, Rockville, MD 20857. Requests should reference Docket No. 80N-0140.

Interested persons may, on or before April 2, 1990, submit to the Dockets Management Branch (address above) written comments regarding this petition or any other matter relating to the common or usual name of diluted juice products. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 80N-0140. The citizen petition and the received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 1990.

Ronald G. Chesemore,
Associate Commissioner for Regulatory
Affairs.

[FR Doc. 90-2097 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90F-0017]

National Starch and Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that National Starch and Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *beta*-amylase to treat modified food starch.

FOR FURTHER INFORMATION CONTACT: Eric L. Flamm, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that National Starch and Chemical Corp., Findern Ave., P.O. Box 6500, Bridgewater, NJ 08807, has filed a petition (FAP 9A4136), proposing that the food additive regulations be amended to provide for the safe use of *beta*-amylase to treat modified food starch.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's

finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: January 24, 1990.

Douglas L. Archer,
Acting Director, Center for Food Safety and
Applied Nutrition.

[FR Doc. 90-2170 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90M-0006]

CIBA Vision Corp.; Premarket Approval of CIBA 2000™ Spherical (Atlafilcon A) Soft (Hydrophilic) Contact Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Atlanta, GA, for premarket approval, under the Medical Device Amendments of 1976, of the spherical CIBA 2000™ Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses for daily wear. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1989, of the approval of the application.

DATES: Petitions for administrative review by March 2, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1080.

SUPPLEMENTARY INFORMATION: On May 3, 1989, CIBA Vision Corp., Atlanta, GA 30360, submitted to CDRH an application for premarket approval of the CIBA 2000™ Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses. The spherical lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters (D) or less that does not

interfere with visual acuity. The spherical lenses range in powers from -20.00 D to +12.00 D and are to be disinfected using a heat, chemical, or hydrogen peroxide lens care system.

On October 20, 1989, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On December 28, 1989, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ-460), address above. The labeling of the CIBA 2000™ Spherical (atlatilcon A) Soft (Hydrophilic) Contact Lenses states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be used in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the *Federal Register*. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate

in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 2, 1990, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commission of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 23, 1990.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 90-2168 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90M-0005]

Storz Ophthalmics, Inc., Premarket Approval of Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Storz Ophthalmics, Inc., Clearwater, FL, for premarket approval under the Medical Device Amendments of 1976 (the amendments) of the Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1989, of the approval of the application.

DATES: Petitions for administrative review by March 2, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1212.

SUPPLEMENTARY INFORMATION:

On November 14, 1988, Storz Ophthalmics, Inc., Clearwater, FL 34616, submitted to CDRH an application for premarket approval of the Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses (IOL's). These devices are indicated in patients 60 years of age and older: (1) where a cataractous lens has been removed following primary intracapsular cataract extraction (ICCE), (2) after a primary extracapsular cataract extraction (ECCE) where there is a structural reason that the anterior chamber lens is preferred to a posterior one, or (3) in a secondary implant procedure. Implantation after primary ECCE should be performed only after the physician has compared the published results of the anterior chamber lens with posterior chamber lenses. The devices are available in a range of powers from 4 diopters (D) through 34 D in 0.5-D increments.

On October 19, 1989, the Ophthalmic Devices Panel, and FDA advisory committee, reviewed and recommended approval of the application. On December 28, 1989, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Under the amendments, IOL's are regulated as class III devices (premarket approval).

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Nancy C. Brogdon (HFZ-460), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request

either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the *Federal Register*. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 2, 1990, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 23, 1990.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 90-2169 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Hearing: Reconsideration of Disapproval of Mississippi State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration, (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on March 13, 1990, in Suite 723, 101 Marietta Tower, Atlanta, Georgia to reconsider our decision to disapprove Mississippi State Plan Amendment 88-14.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the Docket Clerk on or before February 15, 1990.

FOR FURTHER INFORMATION CONTACT: Docket Clerk, HCFA Hearing Staff, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207, Telephone: (301) 966-4471.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove Mississippi State plan amendment (SPA) number 88-14.

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid Agency that informs the agency of the time and place of the hearing and the issues to be considered. (If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.)

Any individual or group that wants to participate in the hearing as a party must petition the Hearing Officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the Hearing Officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c).

If the hearing is later rescheduled, the Hearing Officer will notify all participants.

Mississippi's submission of SPA 88-14 seeks protection under the moratorium provisions of the Deficit Reduction Act of 1984 (DEFRA) for the use of certain resource policies for the period of October 1981 to September 1982.

The issues in this matter as whether: (1) The use of these resource policies during the period in question violates the comparability requirements of the Medicaid program (section 1902(a)(17) of the Act), and (2) the policies qualify for protection under the DEFRA moratorium.

The Secretary is prohibited from taking certain adverse actions against States for using more liberal income and resource methods than those of the cash assistance programs (Aid to Families with Dependent Children (AFDC) and Supplemental Security Income (SSI)) for determinations of eligibility for the medically needy and limited categorically needy groups (section 2373(c) of DEFRA). In cases where the

requirements for moratorium protection are met, such protection can be granted for the period of October 1, 1981, through February 17, 1989.

Mississippi has submitted this amendment for protection under the DEFRA moratorium. The amendment includes 209(b) resource methodologies used by the State between October 1981 and September 1982 as applied to individuals eligible for Medicaid under a special income level. In July 1981, Mississippi converted from a 209(b) State to a 1634 State.

Prior to the conversion, the State had between 18 months and 2 years to prepare for it. This preparation period included time for the State to redetermine eligibility for individuals using the new 1634 rules in place of the old 209(b) rules. The State had asked for a transition period to permit it to use its 209(b) eligibility rules for some recipients for a period of time after the conversion actually took place. However, the State was informed that no transition period could be granted and that 1634 rules must be used as of the month in which the State's conversion was effective.

In spite of the fact that Mississippi was not permitted to use its 209(b) rules after July 1981 (the month of conversion), the State continued to use its 209(b) rules for certain members of the special income level group. Essentially, individuals eligible under the 209(b) rules were continued on the eligibility rolls until redeterminations could be made under the 1634 status rules based on the regular redetermination schedule. Since a period of time elapsed before all redeterminations were made, there was a period between October 1981 and September 1982 when the State was using two sets of methodologies; the 209(b) methodologies and the SSI rules.

Quality control (QC) reviews conducted during this period identified 12 cases where the State had not redetermined eligibility using SSI rules required in a 1634 State which resulted in the cases being found in error. These cases represented over 50 percent of the total cases in error significantly contributing to the State's 5.71 percent payment error rate. This rate was over the target error rate of 5.0663 percent and resulted in a disallowance of \$732,509. The State has requested a waiver of this disallowance based on the special circumstances surrounding its conversion to a 1634 State. It is this disallowance which the State is attempting to reverse via submittal of SPA 88-14. The State is requesting protection under the DEFRA moratorium

for use of two different resource methodologies for individuals eligible under a special income level simultaneously during the period from October 1981 to September 1982.

The effect of the simultaneous use of two different resource methodologies for individuals eligible under a special income level is that during the period for which the State is requesting DEFRA moratorium protection, some individuals in the group would have their eligibility determined under the State's outdated 209(b) rules, while others would have eligibility determined under the State's current 1634 rules. This is contrary to the requirements of the Medicaid statute, which provides that individuals within groups must be treated comparably when determining eligibility (section 1902(a)(17) of the Act).

The DEFRA moratorium specifically applies to methodologies used by a State during the period covered by the moratorium. HCFA believes the DEFRA moratorium does not provide protection in situations where the comparability requirements of section 1902(a)(17) are violated, because the comparability requirements do not constitute a methodology. Methodologies are the processes used to determine countable income and resources. Comparability, by contrast, requires that the same methodologies be used for all members of an eligibility group. While either the State's 209(b) rules or its 1634 rules can be considered as methodologies, HCFA believes that the use of both sets of rules at the same time is not a methodology as contemplated by the DEFRA moratorium provision. Rather, HCFA believes the simultaneous application of two sets of rules to different members of the same eligibility group is a violation of the comparability requirements of section 1902(a)(17), and thus cannot be protected under the DEFRA moratorium.

The notice to Mississippi announcing an administrative hearing to reconsider the disapproval of its State plan amendment reads as follows:

January 19, 1990.

J. Clinton Smith, M.D., M.P.H.
Director, Division of Medicaid,
Office of the Governor,
Suite 801,
Robert E. Lee Building,
239 North Lamar Street,
Jackson, Mississippi 39201-1311

Dear Dr. Smith: I am advising you that your request for reconsideration of the decision to disapprove Mississippi State plan amendment (SPA) 88-14 was received on December 20, 1989. Mississippi SPA 88-14 seeks protection under the moratorium provisions of the Deficit Reduction Act of 1984 (DEFRA) for the use of certain resource

policies for the period of October 1981 to September 1982.

The issues in this matter are whether: (1) The use of these resource policies during the period in question violates the comparability requirements of the Medicaid program (section 1902(a)(17) of the Social Security Act (the Act)) and (2) the policies qualify for protection under the DEFRA moratorium.

I am scheduling a hearing on your request to be held on March 13, 1990, at 10:00 a.m. in Suite 723, 101 Marietta Tower, Atlanta, Georgia. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR part 430.

I am designating Mr. Stanley Katz as the presiding officer. If these arrangements present any problems, please contact the Docket Clerk. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the Docket Clerk of the names of the individuals who will represent the State at the hearing. The Docket Clerk can be reached at (301) 966-4471.

Sincerely,

Louis B. Hays,

Acting Administrator.

(Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: January 19, 1990.

Louis B. Hays,

Acting Administrator Health Care Financing Administration.

[FR Doc. 90-1804 Filed 1-30-90; 8:45 am]

BILLING CODE 4120-03-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of March 1990:

Name: National Advisory Council on Health Professions Education

Date and Time: March 26-27, 1990, 9 a.m.

Place: Conference Room G and H, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Open on March 26, 9 a.m.-12 noon.

Closed for Remainder of Meeting.

Purpose: The Council advises the Secretary with respect to the administration of programs of Financial assistance for the health professions and makes recommendations based on its review of applications requesting such assistance. This

also involves advice in the preparation of regulations with respect to policy matters.

Agenda: The open portion of the meeting will cover welcome and opening remarks, report of the Acting Administrator, Health Resources and Services Administration, report of the Director, Bureau of Health Professions, financial management and legislative update, and future agenda items. The meeting will be closed at 1:30 p.m. on March 26 for the remainder of the meeting for the review of applications for financial assistance for Grants for Graduate Training in Family Medicine, Area Health Education Centers, Faculty Development in Family Medicine, Faculty Development in General Internal Medicine and Pediatrics, Physician Assistants, Two-year Programs of Medicine or Osteopathy, Health Careers Opportunity Program, Geriatric Education Centers, Health Administration and Public Health Capitation. The closing is in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C. Code, and the Determination by the Acting Administrator, Health Resources and Services Administration, pursuant to Pub. L. 92-463.

Anyone requiring information regarding the subject Council should contact Ms. Wilma J. Johnson, Executive Secretary, National Advisory Council on Health Professions Education, room 8C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6880.

Agenda Items are subject to change as priorities dictate.

Dated: January 26, 1990.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 90-2223 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-15-M

National Institutes of Health

Establishment of the Training Grant and Career Development Review Committee

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), and section 402(b)(6) of the Public Health Service Act, (42 U.S. Code 282(b)(6)) as amended, the Acting Director, NIH, announces the establishment, effective February 1, 1990, of the Training Grant and Career Development Review Committee.

The Training Grant and Career Development Review Committee shall be responsible for advising the Director, NIH, and the Director, National Institute of Neurological Disorders and Stroke, concerning training and career development programs and activities in the areas of neurological disorders and stroke. The committee provides a primary review of National Research Service Award applications and Clinical Investigator Development Award

applications in the aforementioned areas. The committee will also provide information concerning future manpower needs in the basic and clinical neurological sciences.

Duration of these committees is continuing unless formally determined by the Director, NIH, that termination would be in the best public interest.

Dated: January 25, 1990.

William F. Raub,

Acting Director, NIH.

[FR Doc. 90-2203 Filed 1-30-90; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Alcohol, Drug Abuse, and Mental Health Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HM, Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), of the statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 36163-7, August 19, 1975, as amended by 54 FR 48032, November 20, 1989) is amended to reflect a reorganization of the National Institute of Mental Health, ADAMHA. The reorganization retitles the Division of Basic Sciences.

Section HM-B, Organization and Functions, is amended as follows:

Delete the title for the *Division of Basic Sciences (HMM2)*, and substitute the following title: *Division of Basic Brain and Behavioral Sciences (HMM2)*.

Dated: January 18, 1990.

Frederick K. Goodwin,

Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 90-2162 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-20-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. N-90-3007; FR-2749-N-01]

Proposed Change of Jurisdictional Responsibility

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development is changing the jurisdiction for oversight and monitoring of Puerto Rico and the Virgin Islands to Region IV (Atlanta) from Region II (New York). This notice includes cost-benefit

information required to be published in the *Federal Register* under section 7(p) of the Department of Housing and Urban Development Act.

DATE: Effective Date: May 1, 1990.

FOR FURTHER INFORMATION CONTACT:

Edwin I. Gardner, Deputy Under Secretary for Field Coordination, Department of Housing and Urban Development, Washington, DC 20410, 202-755-7426 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: In accordance with section 7(p) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(p), the Department of Housing and Urban Development is hereby publishing a proposed plan to change the jurisdictional responsibility of Puerto Rico and the Virgin Islands to Region IV (Atlanta) from Region II (New York) and related cost-benefit information.

A. Introduction and Background

The Department of Housing and Urban Development proposes to change the jurisdictional responsibility for the oversight of the Commonwealth of Puerto Rico and the Virgin Islands to Region IV (Atlanta) from Region II (New York). The purpose of this change is to strengthen the oversight, monitoring and accountability of the administration by Regional staff of the Department's programs in both Puerto Rico and the Virgin Islands.

B. Description of Proposed Changes

The programmatic and management authorities exercised currently by the New York Regional Office over the Department's Caribbean Office which, as the local field office, has responsibility for the administration for HUD programs in both Puerto Rico and the Virgin Islands will be transferred to the Atlanta Regional Office. This change will have no effect on the roles and responsibilities of the Caribbean Office over program operations in either Puerto Rico or the Virgin Islands. There will be no impact on the structure of or the resources presently allocated to the Caribbean Office. However, the implementation of this proposal will create and result in new reporting relationships—i.e., the Caribbean Office will report to the Atlanta Regional Office for policy and program guidance and direction. Additionally, this change will add another Category A office (responsibility for all HUD programs) to those already under the jurisdiction of the Atlanta Regional Administrator/Regional Housing Commissioner. There will be no staffing impact in either the New York Regional Office or the

Atlanta Regional Office that cannot be accommodated by increases already projected currently. New York staff whose duties involve the monitoring and oversight of specific Caribbean Office activities will be redirected to servicing other programmatic issues within their respective program areas. At the time of the jurisdictional transfer, there will be a transfer of staff years from Region II to accommodate the increased monitoring responsibilities being assumed by Region IV.

Cost-Benefit Information

Personnel

Headquarters has reviewed the jurisdictional transfer with comments from the New York Regional Office regarding the impact on current personnel. All Regional program areas were surveyed to ascertain the amount of resources dedicated to Puerto Rico and the Virgin Islands oversight functions. The survey found that no staff member was dedicated solely to these oversight functions. However, a number of staff in all program areas performed a variety of oversight activities as part of their overall responsibilities.

Consequently, the survey found that a total of 10.1 staff years were utilized in performing these monitoring functions by all program areas in FY 1989. Since no employees were identified as being engaged solely in these oversight and monitoring functions, there will be no transfer of personnel from Region II to Region IV and therefore no relocation costs will be incurred. There will be a prorated staff year transfer to accommodate the new responsibilities being assumed by Region IV. This is an internal administrative procedure which will have no impact on HUD staffing requirements.

Travel

A total of 86 individual trips were planned for travel to the Caribbean from the mainland on monitoring or other assignments during FY 1989. Some of these trips were cancelled because of Hurricane Hugo. After all vouchers have been processed, the Region projects expenditures of \$70,000. Travel funds obligated by the Caribbean Office total \$70,760 for travel to the mainland. Total travel funds expended during FY 1989 on travel to and from Puerto Rico and the Virgin Islands will be approximately \$140,000. It is estimated that travel costs will be the same or somewhat less after the jurisdictional change is implemented because of reduced lodging costs in Atlanta.

Miscellaneous Administrative Costs

Other areas reviewed for possible impact were telecommunications and space. It was found that there will be no additional costs incurred in either of these areas.

Impact on Local Economies

Because there will be no transfer of personnel arising out of this jurisdictional change, there will be no impact on either of the local economies involved.

Impact on the Quality of Services

The Department anticipates a positive impact on the quality of services provided to both Puerto Rico and the Virgin Islands.

This will result from both jurisdictions being brought closer to the senior officials in the Atlanta Regional Office who will have the oversight responsibility and overall jurisdiction for the administration of HUD programs for the Caribbean Field Office. There will be no diminution of services to clients in either Puerto Rico or the Virgin Islands.

Authority: Section 7(p) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(p).

Dated: January 22, 1990.

Jack Kemp,

Secretary.

[FR Doc. 90-2217 Filed 1-30-90; 8:45 am]

BILLING CODE 4210-32-M

Office of Administration

[Docket No. N-90-3008]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.
ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the

proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 24, 1990.

John T. Murphy,

Director, Information Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Requisition for Disbursement of section 202 Loan Funds.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: HUD-92403-EH will be used by the non-profit borrower entity to obtain disbursement on its HUD-funded building loan under the section 202 Housing Program for the Elderly or Handicapped. Its use during the construction period will enable the borrower to obtain funds to settle his obligations or reimbursement in a timely manner.

Form Number: HUD-92403-EH.

Respondents: Non-Profit Institutions.

Frequency of Submission: On Occasion.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Form HUD-92403-EH.....	400		12		.5		2,400

Total Estimated Burden Hours: 2,400.

Status: Extension.

Contact: Aretha Williams, HUD, (202)

755-5866, John Allison, OMB, (202)

395-6880.

Dated: January 24, 1990.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Public Housing Development Cost Containment.

Office: Public and Indian Housing.

Description of the Need for the Information and Its Proposed Use: Public Housing Authorities may request revisions to the cost guidelines for their market area or

establish a separate market area for their jurisdictions by providing supporting documentation to the local HUD Field Office.

Form Number: None.

Respondents: State or Local Governments and Non-Profit Institutions.

Frequency of Submission: On Occasion.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Request Revision.....	3		1		16		48

Total Estimated Burden Hours: 48.
Status: Reinstatement.
Contact: William C. Thorson, HUD, (202) 755-6460, John Allison, OMB, (202) 395-6880.
Dated: January 24, 1990.
 [FR Doc. 90-2125 Filed 1-30-90; 8:45 am]
 BILLING CODE 4210-01-M

Office of Housing

[Docket No. N-90-3005]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Housing, HUD.
ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management

Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35). HUD has requested that OMB complete its review within seven days.

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the

proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 25, 1990.

John T. Murphy,

Director, Information Policy and Management Division.

Proposal: Owner Certificate on Low-Income Housing Tax Credits.

Office: Housing.

Description of the Need for the Information and Its Proposed use: The submissions will tell HUD participants in HUD programs will also receive LIHT credits and enable HUD to adjust its mortgage insurance and subsidy commitments to reflect the tax credit's rent restrictions and investor's equity contributions. The adjustments will limit HUD's subsidy costs and mortgage insurance commitments to amounts needed for project feasibility and preclude owners and developers from making excessive profits by combining tax credits with HUD programs.

Form Number: None.

Respondents: Owners/developers who will receive tax credits, participate in a HUD program and request HUD approval of one of the actions listed in the proposed notice's Attachment 1.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	x	Burden hours
1,170			1		1/2		585

Total Estimated Burden Hours: 585.
Status: Revision.

Contact: Sue Donahue, HUD, (202) 755-5547, John Allison, OMB, (202) 395-6880.

Date: January 25, 1990.

Supporting Statement to SF-83, Owner Certification on LIH Tax Credits

A. Justification

1. Multifamily projects participating in HUD's mortgage insurance or subsidy programs can also receive Low Income Housing Tax Credits from the states. They can receive credits for building, acquiring or rehabbing units that will be occupied by low-income families. The credit is taken annually for 10 years. The maximum annual credit a project may receive is 4 percent of acquisition costs and 9 percent of construction or rehab costs.

a. To receive and take the credit, owners must agree to lease at least either: (1) 20 percent of the units to families with incomes at/below 50 percent of the area median incomes (20/50 option); or (2) 40 percent of the units to families with incomes below 60 percent of the area median income (40/60 option). The owner chooses which option to apply and which units will be rent restricted. For either option, the owner may choose to exceed the minimum (20/40 percent) low-income use and receive credit on the additional units.

b. The tax credit law limits a tenant's rent to no more than 30 percent of the income limit (50/60 percent of the median selected by the owner. For example, if an owner chooses the 20/50 option, a tenant's gross rent may not exceed 30 percent of 50 percent of area median income, adjusted for family size.

c. Projects receiving tax credits allocations are generally syndicated as limited partnerships. Investors pay cash up front or over a few years in return for ownership interests and the right to take a proportionate share of the project's tax credit on their personal tax returns. Generally, investors contribute cash equal to five times the annual credit amount.

Since tax credits are allocated by States and owners are not now required to tell HUD of tax credit allocations, HUD does not know which projects have credits or the amount of the credits. If a project receives credits without HUD's knowledge, it is very likely that HUD will assume excessive mortgage insurance risk or award more assistance than a project needs.

a. **Excessive Mortgage Insurance Risk.** If HUD is not aware that a project has a tax credit allocation, HUD could

insure/coinsure a mortgage that is higher than needed or higher than the restricted tax credit rents can support.

• *The mortgage could be higher than rents can support* because HUD's feasibility analysis and appraisals will be based on market rents but the tax credit rules will limit actual rents on all or some units to significantly lower amounts. HUD will now know how many units or which units are rent-restricted or the rent option the owner has selected. *Result:* Increased potential for defaults and claims against the FHA insurance funds.

• *The mortgage could be higher than needed to support construction or rehab* because HUD processing will be based upon total costs and won't reflect the private capital raised by the tax credit. *Result:* Limited insurance authority is wasted and any subsequent claim on the FHA insurance funds is unnecessarily high.

b. *Excessive Assistance Awarded.* If HUD does not know that a project has a tax credit allocation, assistance could be excessive because HUD would likely:

• Award tenant rent subsidies based on market rents, when the owner would be charging significantly lower rents. Again, unless the owner submits the information requested by our Notices, HUD would not know that rents are restricted or the amount of the reduction.

• Allocate Flexible Subsidy and other repair assistance based on total rehab needs, even though investor contributions could meet all or part of these needs.

• Award tenant rent subsidies to support mortgages that are unnecessarily high for reasons noted in Paragraph a above. *Result:* Scarce subsidy dollars are wasted.

2. HUD staff will use the information to assure that HUD does not award excessive subsidies or assume undue risk when owners combine the Low Income Housing Tax Credit with HUD's mortgage insurance or subsidy programs.

a. *Certification on Participation in LIHTC Program.* All applicants for HUD assistance or mortgage insurance must disclose whether they plan to participate in the LIHTC program. The disclosure is submitted to the HUD Field Staff/Coinsuring Lender/PHA who processes the transaction involved. If the applicant's response is:

• Negative, the applicant merely photocopies and signs the certification in Attachment 3 of the Notice. No additional submission is required.

• Positive, the applicant must submit the information listed in Attachment 2 of the Notice.

b. *Materials Submitted by Tax Credit Participants.* These submission requirements are listed in Attachment 2 of our proposed Notice. Initially, HUD Field Offices and lenders will pass these materials to HUD Headquarters and HUD Headquarters will use them as described below. Later, after review procedures have been tested and finalized, HUD Field Staff will perform these reviews.

• *Tax Credit Terms* (Item 1 of Attachment 2). HUD needs this information to accurately estimate a project's income. If income is over/understated, HUD will assume excessive mortgage insurance risk or award more assistance than needed, as explained in Paragraph 1 above.

• *Information on Sources and Uses of Funds* (Items 1a, 2, 3, 4, and 5). This information will show HUD the total funding available to meet a project's development, rehab or operating costs. HUD will adjust assistance or insurance commitments to reflect the private capital raised by the tax credits. Without this information, HUD's commitments would be higher than needed as they would be based on an unadjusted needs figure.

• *Applicant Agreement to Notify HUD of Subsequent Changes in Information Submitted.* If applicants submit unupdated information, HUD's subsidy and mortgage calculations will more accurately reflect project needs. If an applicant does not report changes that occur and those changes cause subsidy/mortgage amounts to be excessive, the owner certification will give HUD a basis to pursue penalties or other corrective action.

3. The information collection burden associated with this certification is minimal, so there has been no consideration of the use of improved information technology to reduce the burden.

4. Neither this or any similar information is now available to HUD. While HUD currently does not see this information, most tax credit applicants will have already compiled the information Attachment 2 requests. They will have done so to assess the feasibility of their proposal, to prepare a syndication offering or to submit their credit applications to the states. To keep applicant burden to a minimum, we will accept photo copies of such submissions.

5. See #4 above.

6. The burden for all respondents, including small businesses, is minimal.

7. If information were collected less frequently than proposed by our Notice, HUD would not have the information it needs to accurately determine mortgage

insurance and assistance needs. (See Items 1a and 1b above.)

a. Our notice requires applicants to submit the information before HUD or its agent executes documents locking HUD into a specific amount of mortgage insurance or assistance or setting forth conditions on which HUD will approve a specific transaction. If information were submitted at a later point, HUD would not be able to adjust its commitments to reflect the information.

b. Generally, an applicant need submit information only once. If an applicant submits the information at one stage (e.g. conditional commitment), the applicant need submit the information again only if it changes.

8. See #7 above.

9. Consultation with persons outside of HUD was not considered necessary, given the limited scope of the information to be collected.

10. HUD does not assure confidentiality.

11. Not applicable.

12. Annual cost to HUD and to respondents are estimated below.

Respondent costs	HUD costs
Time required/response = 1/2 hour	Time review = 1 hour
Cost/response = \$10 (\$42,000 salary)	Cost/review = \$16 (\$33,000 salary)
Total responses/year = 1170	Total reviews/year = 1170
Total cost = \$11,700	Total cost = \$18,720

13. The information collection burden hours was estimated to be:

Number of respondents = 1170

Number of responses/respondent/year = 1

Total number of responses per year = 1170

Time required/response = 1/2 hour

Total annual burden = 585 hours

The number of respondents was estimated using preliminary 1988 data from state credit agencies. The data shows that during 1988 842 of the 3262 projects receiving 1988 tax credit allocations participated in a HUD mortgage insurance or subsidy program (236, BMIR, Section 8, Mod Rehab, Rent Sup). Another 34 projects participated in the HODAG program. We estimated total responses by trending 1988 data to recognize: (1) Increased usage of credit authority; (2) that Nov' 89 tax credit legislation precludes Mod Rehab projects from receiving 1990 credit allocations; (3) that HODAG generally did not make new awards after 1988 and, hence, subsidy commitments will already be locked in on most HODAG projects; and (4) that projects can stay in

the processing pipeline for one to two years.

The 1170 respondents was estimated as shown below.

Year of tax credit authority	Total HUD-related projects receiving credit allocations	Percent of col. 2 having Atmt. 2 action in '90	Total responses (col 2x3)
(1)	(2)	(3)	(4)
1988	842	20	168
1989	1000	70	700
1990	720	40	288
			1,156
			HODAG + 14
			1,170

14. Estimated respondent burden hours and cost to government differ from the hours and costs we estimated in 1988 when requesting OMB approval of tax credit submissions by applicants for FHA full insurance (OMB No. 2502-0377). The differences are due to the following facts.

a. Our 1988 submission significantly overestimated the number of respondents. While we estimated 580 submissions would be required, only about 20 submissions were made between 2/89 and 12/1/89.

b. The proposed notice will require tax credit disclosure on more transactions. While our 1988 memo required disclosure only in conjunction with mortgage insurance applications, our new notice will require disclosure on all of the transactions listed in the Notice's Attachment 1.

c. While our 1988 SF-83 estimated that each respondent would make two submissions per year, under the proposed notice each respondent will generally submit Attachment 2's data only once in any year. (See Item 7b Above.)

d. Respondent's cost per submission is reduced because we assumed a \$42,000 salary rather than the \$62,400 salary used in our 1988 submission. Since the data is already available, it can be compiled by mid-level staff.

e. HUD review time is increased because reviewing the Sources and Uses Statement, which was not required by the 1988 policy, will consume additional HUD time.

15. Not applicable.

B. Collection of Information Employing Statistical Methods

This information collection will not employ statistical methods.

Combining Low Income Housing Tax Credits (LIHTC) with HUD Programs

I am asking your assistance in assuring that developers and owners do not receive excessive profits or subsidies or create undue mortgage insurance risks by combining tax credits with HUD's subsidy or mortgage insurance programs. Credits, subsidies and mortgage insurance are all limited commodities and I want to use these scarce resources to maximize production and preservation of affordable housing—not to generate excessive profits for developers or owners.

In a few instances, developers/owners have realized large profits because either: (a) They did not disclose they would receive tax credits; or (b) mortgage insurance or subsidy processing did not recognize the tax credits' rent restrictions or the funds raised by selling ownership interests in tax credit projects. To address these deficiencies, I am asking that HUD staff, coinsuring lenders and PHAs modify processing to incorporate the procedures set forth in this memo. *Important:* Each HUD Office should mail its PHAs a copy of this letter, with a cover letter directing them to take these actions on transactions PHAs process.

Effective immediately, before taking any of the actions listed in Attachment 1, your staff/ PHAs/coinsuring lenders must: (1) Ask the applicant whether the current or any prospective owner plans to participate in the LIHTC program; and (2) obtain HUD Headquarters review of all cases that will use tax credits.

• If the applicant's response is *POSITIVE*, require the applicant to submit the information listed in Attachment 2. (Note: Attachment 2 supercedes and replaces the submission requirement now included on page 4 of our February 2, 1988 memo and in Coinsuring Lender Letter 88-2 regarding processing tax credit transactions. These requirements apply to all tax credit projects—not just those exceeding the 1988 40 percent threshold.)

• If the applicant's response is *Negative*, require the applicant to sign the certification in Attachment 3 to this memo. Note that the certification requires the applicant to immediately notify HUD if the applicant's plans change and the project receives or applies for tax credits.

Submit cases for Headquarters' review before approving any of the actions listed in Attachment #1, but after your staff/ the PHA/ the coinsuring lender has completed all analysis required by outstanding instructions. PHAs should submit cases through HUD Field Offices. Coinsuring lenders should submit cases directly to HUD Headquarters. When submitting cases to Headquarters:

• Send the package to the program office having responsibility for the transaction currently being processed, but identify all HUD programs in use/expected to be used at the project.

Example: If a project is now seeking mortgage insurance but will later seek section 8, submit the case to the Office of Insured Housing Development but note in your transmittal that the applicant also plans to seek section 8. My Development staff will

coordinate with the appropriate Headquarters section 8 staff.

• Send all information the owner submitted pursuant to Attachment 2 and all documents related to the financial aspects of the transaction being processed.

Note: Once Headquarters has reviewed any tax credit information and directed that processing proceed, a project must be resubmitted during any subsequent processing only if the tax credit information changes or Headquarters' review letter specifically required resubmission.

The November 21 Budget Reconciliation Bill made several changes to the LIHTC program. Attachment (4) is a copy of the legislation. Among other things, the new law: (1) Requires tax credit applicants to disclose all state, local, or federal subsidies; and (2) directs the states to develop allocation and selection criteria, consider all sources and uses of funds and limit credit allocations to the amount needed to make projects feasible. Headquarters staff will be working with Treasury and the National Council of State Housing Agencies to develop procedures for coordinating the states' underwriting with HUD's reviews. Meanwhile, I would like you or your office's tax credit liaison to meet with the state agencies responsible for allocating tax credits in your jurisdiction. At the meeting, you should:

• Ask the credit agency to describe any application and allocation procedures they now use and their plans for implementing the November 21 legislation's underwriting and allocation requirements.

• Determine how the use of HUD mortgage insurance or HUD subsidies will affect the credit agency's elevation of a tax credit application.

• Obtain copies of any forms the agency uses to issue preliminary approvals, reserve, or allocate credits.

• Ask the agencies to notify your staff/the Coinsuring Lender/the PHA (for Mod Rehab or PBA certs) whenever they learn that a tax credit applicant is participating in a HUD mortgage insurance or subsidy program.

• Alert the credit agency to the new legislation prohibiting Mod Rehab projects from receiving 1990 tax credit allocations. (See legislation in Attachment 4, page 9397, bottom of first column.)

Understanding the states' procedures should help you identify which projects are likely to receive credits and the potential for excess profits. It may also give you ideas on how HUD and states' processing can be better coordinated. If your meetings generate such ideas, please convey these ideas to Sue Donahue in room 6168, at 755-5547 or Fax number 755-2533.

Thanks for your cooperation on this important matter.

C. Austin Fitts,

Assistant Secretary for Housing-Federal Housing Commissioner.

Attachments (4)

Actions Requiring Certifications as to Participation in LIHTC Program

HUD field staff, coinsured lenders and PHAs must obtain an applicant's certification as to whether the project will participate in

the LIHTC program before taking any of the actions listed in this attachment. Items 1 and 2 apply only to the programs named there. All other items may apply to more than one program—e.g., coinsurance and full insurance.

1. *Project-Based Certificates*: establishing initial contract rents (including exception rents); signing AHAPs; approving special rent adjustments; approving transfers of property ownership or subsidy contracts.

2. *Mod Rehab (Regular and SRO)*: Use actions listed in Item 1. While the Budget Reconciliation Bill provides that 1990 tax credit authority may not be allocated to Mod Rehab projects, Mod Rehab projects that received allocations of 1989 or earlier tax credits authority may still use credits. Since some projects with these earlier credit allocations will be in the Mod Rehab pipeline for at least another 18 months, the tax credit certification must be obtained from Mod Rehab applicants.

3. *Mortgage Insurance*: issuing a SAMA/feasibility letter or a conditional/firm commitment under section 207, 220, 221(d)(3), 221(d)(4), 223(f), 231 or 241.

4. *Rent Increases*: Before approving special adjustments or using an operating needs formula for projects that use the section 8 Annual Adjustment Factor (AAF) rent method.

5. *Residual Receipts*: Before releasing residual receipts.

6. *Flexible Subsidy*: Before recommending or approving reservations, contract increases or extensions, or new contracts. Before depositing Flexible Subsidy Funds in a working capital fund/replacement reserve account when closing-out a Flexible Subsidy contract.

7. *Ownership Changes*: Issuing preliminary or final approval of TPAs; assigning subsidy contracts to new owners.

8. *Mortgage Relief*: Approving or recommending approval of workouts/mortgage modifications/partial payment of claims.

9. *Prepayment Plans of Action*: Recommending Headquarters approval of plans of action required under 1987 or subsequent prepayment legislation.

10. *Foreclosure Sales*: Executing a use agreement, AHAP or HAP contract when HUD is outbid at a foreclosure sale.

11. *PD Negotiated Sales*: Before recommending Headquarters approval of any non-competitive sale. (Request the tax credit certification during your preliminary discussions.)

12. *PD Competitive Sales (When bids are opened in the Field Office)*: Before executing a sales contract, AHAP or HAP contract. (Headquarters will request tax credit certification and information when bids are opened in Headquarters.)

13. *HODAG*: Issuing preliminary approval of project applications; executing or amending Grant Agreements; approving an ownership change; recommending waiving a regulation.

Materials LIHTC Participants Must Submit

1. Brief summary of the terms on which the applicant will participate in the LIHTC program. Include:

a. The annual credit amount, the date the 10-year credit period will begin and the credit percentages awarded by the state

b. Which income eligibility limit will apply (40/50/60 percent of median income)

c. List of units for which credits will be claimed, showing number of units in each bedroom size and initial tax credit rent limit for each unit size. (Note: Nov '89 legislation sets the rent limit based on the median income of a "hypothetical" household having 1.5 persons per bedroom. Under previous law, rent cap was based upon the actual size of the household occupying the unit.)

2. Copy of (a) IRS 8809, Low Income Housing Credit Allocation Certification; or (b) a report on the status of any tax credit allocation still in process and a copy of any credit agency reservation form or other document indicating agency's intent to award credits to the project.

3. Whether credit will be claimed by current owners or sold to new owners.

4. List of all federal/state/local government insurance, loan, grant or subsidy programs in which the applicant plans to participate and any grants or below-market loans expected to be received from non-government sources. For each loan, give interest rate, monthly debt service, loan amount and loan term.

5. Sources and Uses of Funds Statement, itemizing: (a) All funds available; (b) all purposes for which funds will be disbursed; and (c) dates of any investor contributions are due.

6. A Statement in which the applicant agrees to promptly notify the HUD Field Office of any change in the information provided pursuant to this attachment.

Note: The following language must be included in the submission. The applicant's signature must appear immediately below this warning.

Warning: It is a crime to knowingly make false statements to a federal agency. Penalties upon conviction can include a fine and imprisonment. For details see title 18 U.S. Code, sections 1001 and 1010.

Owners Certification that Project will not Participate in LIHTC Program

To: HUD Field Office

ATTN: Housing Director

RE: Project No. _____

Project Name: _____

1. I certify that neither I nor any other representative of the project identified above currently intends to participate in the LIHTC program with regards to the subject project.

2. If plans change and I or another representative of the project decide to participate in the LIHTC program with regards to the subject project, I will notify you in writing immediately following our decision to participate.

Warning: It is a crime to knowingly make false statements to a federal agency. Penalties upon conviction can include a fine and imprisonment. For details see title 18 U.S. Code, sections 1001 and 1010.

Signature _____

Date _____

Name _____

Title _____

[FR Doc. 90-2216 Filed 1-30-90; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ 020-41-5410-ZAHK; AZA-24247]

Mineral Interest Application

ACTION: Notice of receipt of conveyance of mineral interest application AZA-24247.

Notice is hereby given that pursuant to section 209 of the Act of October 21, 1976, 90 Stat. 2757, Douglas Land Corporation has applied for conveyance of the mineral estate described as follows:

Gila and Salt River Meridian, Arizona

T. 5 N., R. 5 W.,

sec. 21, E½;

sec. 22, all;

sec. 23, W½SW¼, SE¼SW¼;

sec. 25, all;

sec. 26, all;

sec. 27, all;

sec. 28, E½;

sec. 33, E½;

sec. 34, all;

sec. 35, all.

Containing 4,920.00 acres, more or less.

The mineral interests will be conveyed in whole or in part upon favorable mineral examination.

The purpose is to allow consolidation of surface and subsurface ownership for the lands described above, where there are no known mineral values or in those instances where the reservation of ownership of the mineral interest in the United States interferes with or precludes appropriate non-mineral development of the lands and such development would be a more beneficial use of the lands than its mineral development.

Additional information concerning this application may be obtained from the Area Manager, Lower Gila Resource Area, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027.

Upon publication of this notice in the Federal Register, the mineral interests described above will be segregated to the extent that they will not be open to appropriation under the public land laws, including the mining laws. The segregative effect of the application shall terminate either upon issuance of a patent or other document of conveyance of such mineral interests, upon final rejection of the application or two years

from the date of the filing of the application, January 19, 1990, whichever occurs first.

Dated: January 19, 1990.

Charles R. Frost,

Associate District Manager.

[FR Doc. 90-2156 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-32-M

Bureau of Reclamation

Proposed Los Vaqueros Project, Contra Costa County, California

AGENCY: Bureau of Reclamation
(Interior).

ACTION: Notice of intent to prepare a draft environmental impact report/ environmental impact statement for the Los Vaqueros Project, Contra Costa County, California.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, and section 21002 of the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation) and the Contra Costa Water District (CCWD) intend to prepare a joint environmental impact report/ environmental impact statement (EIR/ EIS) for the Los Vaqueros Project, California. The primary purposes of the project would be to improve the quality of water supplied to CCWD customers, to minimize seasonal quality changes, and to improve the reliability of the CCWD supply by providing for emergency storage. Secondary purposes of the project are to provide flood control benefits, maintain and enhance fish and wildlife resources, and offer recreational opportunities.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Kleinsmith, Bureau of Reclamation, Mid-Pacific Region, 2800 Cottage Way, Sacramento, California 95825-1898, telephone: (916) 978-5121, or Mr. John S. Gregg, Assistant General Manager, Contra Costa Water District, P.O. Box H20, Concord, California 94524, telephone: (415) 674-8000.

SUPPLEMENTARY INFORMATION: CCWD is proposing to construct a reservoir on Kellogg Creek, south of the city of Brentwood in southeastern Contra Costa County. The project would consist of a reservoir with about 100,000 acre-feet of storage for CCWD, a new point of diversion in the Sacramento-San Joaquin Delta (possibly in conjunction with the current Rock Slough diversion point), associated water conveyance and delivery facilities, pumping plants, and other facilities. The project would

require the realignment of Vasco Road, an important arterial roadway that would be inundated by the project, and relocation of several buried pipelines and electrical power transmission lines. The CCWD-only project includes a dam up to approximately 205 feet high and a reservoir which covers up to about 1,640 acres. The total cost for CCWD's portion of the project is estimated at \$350 million in 1988 dollars.

The Los Vaqueros Project would be funded, built, and operated by CCWD. CCWD may seek an amendment to its existing Water Service Contract I75r-3401 (amended) with Reclamation to accommodate operation of the Los Vaqueros Project and certain repayment conditions. Reclamation would serve as the lead Federal agency responsible for NEPA compliance on the proposed project. Alameda County Flood Control and Water Conservation District Zone 7 (Zone 7) may participate in the project and would fund its portion of the project. Participation by Zone 7 would provide for approximately 40,000 acre-feet of additional storage.

CCWD has followed a staged approach to this environmental documentation for the Los Vaqueros Project as provided by NEPA and CEQA. In 1986, CCWD completed and certified the Stage 1 EIR for the Los Vaqueros Project to evaluate a full range of alternative options for meeting project objectives and to identify impacts of watershed acquisition and management. At the conclusion of the Stage 1 EIR, CCWD narrowed the range of options to reservoir concepts within the Kellogg Creek watershed as the only alternatives capable of achieving all project objectives. CCWD also is currently preparing the Vasco Road and Utility Relocation EIR, pursuant to State CEQA Guidelines, to assess impacts of relocating Vasco Road and several major utility facilities in the project area.

The Stage 2 EIR/EIS will incorporate significant findings from the Stage 1 EIR and Vasco Road and Utility Relocation EIR and present detailed and comprehensive evaluations of the Los Vaqueros Project and alternatives to the project. Zone 7 would prepare its own EIR to evaluate alternative ways to meet its objectives, including participation in the Los Vaqueros Project; these findings would also be incorporated into the Stage 2 EIR/EIS.

Alternatives to the proposed Los Vaqueros Project to be evaluated by CCWD at this time include: No action, two reservoir sites within the Kellogg Creek watershed, and alternative project configurations. Alternative

components of the Los Vaqueros Project include: A reservoir, diversion facilities, conveyance facilities, pumping plants, and water sources. Additional alternatives identified during the scoping process may also be considered in the EIR/EIS if any are determined to be feasible.

Primary impacts that will be evaluated in the EIR/EIS include effects on fish, wildlife, plants, water quality, hydraulics, hydrology, socioeconomics, traffic, air quality, recreation, aesthetics, cultural resources, floodplains, wetlands, and growth.

Three scoping meetings have been scheduled to solicit public input to determine alternatives to the proposed project, the scope of the EIR/EIS, and to identify the significant issues related to the proposed action:

Date: March 20, 1990.

Time: 7 p.m.

Address: Contra Costa Water District Board Room, 1331 Concord Avenue, Concord, California 94524.

Date: March 22, 1990.

Time: 7 p.m.

Address: Antioch City Council Chambers, Third and H Streets, Antioch, California 94509.

Date: March 27, 1990.

Time: 7 p.m.

Address: Livermore City Council Chambers, 3575 Pacific Avenue, Livermore, California 94550.

No further formal scoping activities are planned. Interested public entities and individuals may obtain information on the project and provide input to the draft EIR/EIS. The draft EIR/EIS is expected to be completed and available for review and comment in spring 1991.

Note: For those disabled persons requiring special services, contact Reclamation EEO Officer Curtis Smith at (916) 978-4911. Please notify Mr. Smith as far in advance of the meetings as possible and no later than March 10, 1990, to enable Reclamation to secure the needed services. If a request cannot be honored, the requester will be notified. A telephone device for the hearing impaired is not available.

Dated: January 25, 1990.

Darrell W. Webber,

Assistant Commissioner—Engineering and Research.

[FR Doc. 90-2173 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-09-M

Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the

Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):
PRT 745661

Applicant: San Diego Zoo, San Diego, CA.

The applicant requests a permit to export nine captive-hatched Andean condors (*Vultur gryphus*) to the Instituto Nacional para el Desarrollo de los Recursos Naturales y Renovables (INDERENA), Bogota, Colombia. These birds will be released to the wild in Narino, Colombia, as part of the release program.

PRT 745540

Applicant: St. Augustine Alligator Farm, St. Augustine, FL.

The applicant requests a permit to import 12 pairs of captive-held black caiman (*Melanosuchus niger*) from the El Dorado ranch, Bolivia, for the purpose of captive-propagation. Once imported, the pairs will be sent to six different zoos.

PRT 745655

Applicant: Fossil Rim Wildlife Center, Glen Rose, TX.

The applicant requests a permit to import one captive-born male cheetah (*Acinonyx jubatus*) from the Wassenaar Wildlife Breeding Center, Wassenaar, Holland, for the purpose of captive-propagation.

PRT 746058

Applicant: Alice E. Karl, Sanger, CA.

The applicant requests a permit to capture desert tortoises (*Gopherus agassizii*) in Ward Valley, California, for the purpose of obtaining baseline (pre-relocation) measurements in association with the California Department of Health Services' proposed low-level radioactive waste facility. The applicant intends to capture, attach transmitters, weigh, measure length, mark, and release tortoises and monitor nests and resulting hatchlings for information on nesting productivity and mortalities. Applicant will monitor movements of tortoises, body conditions and reproductive conditions and will rehydrate tortoises suffering from dehydration.

PRT 746056

Applicant: LSA Associates, Inc., Irvine, CA.

The applicant requests a permit to capture, collect hair samples, and release Stephens Kangaroo rats (*Dipodomys stephensi*) in Riverside and San Diego Counties, California, for the purpose of determining the presence or absence of this species on certain lands.

PRT 746049

Applicant: American Honda Motor Co., Inc., Gardena, CA.

The applicant requests a permit to relocate desert tortoises (*Gopherus agassizii*) from one section of land owned by the applicant to land administered by the Bureau of Land Management near Cantil, California. The tortoises will be studied for three years (weighed, measured, marked, blood samples drawn, transmitters attached, etc. . .) and their habitat will be selectively enhanced during the relocation study. Diseased tortoises will be removed from the wild and carcasses will be salvaged.

Documents and other information submitted with these applications are available to the public during normal business hours (7:45 am to 4:15 pm) in Room 430, 4401 N. Fairfax Dr., Arlington, VA 22201, or by writing to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, P.O. Box 3507, Arlington, VA 22203-3507.

Interested persons may comment on any of these applications within 30 days of the date of this publication by submitting written views, arguments, or data to the Director at the above address. Please refer to the appropriate PRT number when submitting comments.

Date: January 26, 1990.

Karen Willson,

U.S. Office of Management Authority.

[FR Doc. 90-2120 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-AN-M

Minerals Management Service

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provision of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's Clearance Officer, at the telephone number listed below.

Comments and suggestions on the requirements should be made within 30 days directly to the Bureau Clearance Officer, Mail Stop 632, Parkway Atrium, 381 Elden Street, Herndon, Virginia 22070-4817; and to the Office of Management and Budget, Interior Department Desk Officer, Washington, DC 20503, telephone (202) 395-7340; (OMB Project Number 1010-0048); with copies to Gerald Rhodes; Chief, Branch of Rules, Orders, and Standards; Offshore Rules and Operations Division;

Mail Stop 646, room 3313; Minerals Management Service; 381 Elden Street; Herndon, Virginia 22070-4817.

Title: Applying for Notices or Permits, 30 CFR 251.5.

OMB Approval Number: 1010-0048.

Abstract: Respondents provide the Minerals Management Service (MMS) with a status report that enables MMS to verify that permit requirements are met, estimate completion dates and determine the quality of data acquired by persons operating under a permit for geological and geophysical exploration for mineral resources and scientific research in the Outer Continental Shelf.

Bureau Form Number: MMS-327.

Frequency: On occasion.

Description of Respondents: Federal OCS permittees.

Estimated completion time: 6.04 hours.

Annual Responses: 255.

Annual Burden Hours: 1,540.

Bureau Clearance Officer: Dorothy Christopher (703) 787-1239.

Dated: December 11, 1989.

William D. Bettenberg,

Associate Director for Offshore Minerals Management.

[FR Doc. 90-2200 Filed 1-30-90; 8:45 am]

BILLING CODE 4310-MR-M

INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

Availability of Final Environmental Assessment and Finding of No Significant Impact

AGENCY: United States Section, International Boundary and Water Commission, United States and Mexico.

ACTION: Notice of availability of final environmental assessment and finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Final Regulations (40 CFR parts 1500 through 1508); and the U.S. Section's Operational Procedures for Implementing section 102 of NEPA, published in the Federal Register, September 2, 1981 (46 FR 44083); the U.S. Section hereby gives notice that the Final Environmental Assessment and Final Finding of No Significant Impact for Placement of Lane Dividers on the Bridge of the Americas (Cordova Bridge), El Paso, Texas are available. A Notice of Finding of No Significant Impact was published in the Federal Register, December 29, 1989 (54 FR 53764-53765) and provided a thirty

(30) day review and comment period before making the finding final.

ADDRESSES: Mr. M.R. Ybarra, U.S. Section Secretary, International Boundary and Water Commission, United States and Mexico, U.S. Section, 4171 North Mesa Street, C-310, El Paso, Texas 79902. Telephone: 915/534-6698, FTS 570-6698.

SUPPLEMENTARY INFORMATION:

Proposed Action

It is proposed that physical lane dividers be placed at the outermost north and south bound traffic lanes of the Cordova Bridge to separate the flow of passenger vehicle traffic from that of commercial trucks. The proposed action would be taken to resolve an international concern regarding the structural integrity of the bridge by reducing the stress on the bridge caused by loaded commercial trucks until rehabilitation can be done.

Alternatives Considered

Six alternatives were considered:

The Preferred Alternative is to install a concrete curb delineating the extreme right-hand lanes into each country for commercial traffic. The curb would be 8" across the top, 12" across the bottom and 12" high. The curb would be precast in 10-foot lengths and rigidly attached to the bridge deck by anchors. Signs designating the right-hand lane of the bridge reserved for commercial traffic only would be placed at strategic locations.

Double Stripe. A painted double stripe was considered as a means of delineating a commercial truck traffic lane. A double solid white stripe signifying no lane change allowed would be painted on the road surface. Signs designating the right-hand lane of the bridge reserved for commercial traffic only would also be placed at strategic locations.

Barrels. Fifty-five-gallon drums filled with sand were considered as an alternative to provide lane delineation. These barrels would be a physical barrier placed along the lane divider stripe. Signs designating the right-hand lane of the bridge reserved for commercial traffic only would also be placed at strategic locations.

Precast Concrete Wall. Concrete highway median barriers (Jersey barriers) were considered as a means of physically separating the truck traffic lane from the passenger traffic. Jersey barriers have bases measuring 2'3" wide, tapering to a narrow top 8" wide and are 2'8" tall. They would be rigidly attached along the lane divider stripe separating the right-hand lane from the remaining

traffic lanes. Signs designating the right-hand lane of the bridge reserved for commercial traffic only would also be placed at strategic locations.

Painted Lane. Completely painting the right-hand lane was considered to designate commercial traffic use only. Signs designating the right-hand lane of the bridge reserved for commercial traffic only would also be placed at strategic locations.

No Action Alternative. Under this alternative, no painting of stripes, lanes, nor placement of physical barriers would be done on the Cordova Bridge. No steps would be taken to separate passenger traffic from commercial traffic on the bridge.

Availability

Single copies of the Final Environmental Assessment and Final Finding of No Significant Impact may be obtained by request at the above address.

Dated: January 18, 1990.

Suzette Zaboroski,
Staff Counsel.

[FR Doc. 90-2201 Filed 1-30-90; 8:45 am]

BILLING CODE 4710-03-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-292]

Certain Methods of Making Carbonated Candy Products; Decision to Review Certain Portions of Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review certain portions of the initial determination (ID) issued on December 8, 1989, by the presiding administrative law judge (ALJ) in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Frances Marshall, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436; telephone 202-252-1089. Hearing-impaired individuals are advised that information about this matter can be obtained by contacting the Commission's TDD terminal, 202-252-1810.

SUPPLEMENTARY INFORMATION: On January 31, 1989, General Food Corporation, Carbonated Candy Ventures, and Pop Rocks, Inc., filed a complaint under section 337 of the Tariff

Act of 1930 (19 U.S.C. 1337) alleging infringement of two U.S. method patents for making carbonated candy by two proposed respondents. The Commission instituted an investigation of the complaint and issued a notice of investigation published in the *Federal Register* on March 8, 1989 (54 FR 9903).

On December 8, 1989, the presiding ALJ issued an ID finding no violation of section 337 in this investigation with regards to U.S. Letters Patent 3,985,910 (the '910 patent) and U.S. Letters Patent 4,001,457 (the '457 patent). He also held the '910 patent invalid.

Complainants General Foods, Carbonated Candy Ventures, and Pop Rocks, Inc., respondents Zeta Espacial, S.A. and Confex, Inc., and the Commission investigative attorney filed petitions for review of the ID, as well as responses to these petitions for review. The Commission did not receive any comments from government agencies.

Having examined the record in this investigation, including the ID, the Commission has determined to review certain issues. Specifically, the Commission will review the issues of: (1) Claim construction, (2) infringement under the doctrine of equivalents, (3) inventorship of the '910 patent, (4) invalidity of the '910 patent due to indefiniteness, (5) invalidity of the '910 patent due to failure to reveal the best mode, and (6) the '910 patent domestic industry finding. The Commission is particularly interested in the following issues:

1. Whether the ALJ's claim construction of step h of claim 1 of the '910 patent and step d of claim 1 of the '457 patent is correct; particularly, whether the ALJ construed those claims in light of Zeta's processes A and B.

2. Whether the ALJ correctly determined that the named inventor of the '910 patent did not invent anything about shock-treating.

3. Whether, as a matter of law, inventorship can be sustained if an element of the patent claim, although deemed unnecessary and inaccurate, is found to be invented by someone other than the named inventor of the patent.

4. Whether respondents have shown by clear and convincing evidence that the named inventor of the '910 patent did not particularly point out and distinctly claim the subject matter he regarded as his invention at the time he filed the '910 patent application.

5. Whether respondents have shown by clear and convincing evidence that the named inventor of the '910 patent concealed his best mode in the patent's specification.

6. Whether complainants practice the '910 patent, as the '910 patent is construed by the ALJ in the ID.

In connection with final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) a cease and desist order that could result in a respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues under review, remedy, the public interest, and bonding, complainants and the Commission investigative attorney are also requested to submit a proposed exclusion order and/or proposed cease and desist order(s) for the Commission's consideration. Written submissions from the parties, and including any proposed orders, must be filed by February 7, 1990, and reply submissions from the parties must be filed by February 14, 1990.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the

Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

ADDITIONAL INFORMATION: Copies of nonconfidential versions of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436; telephone: 202-252-1000.

By order of the Commission.

Issued: January 24, 1990.

Kenneth R. Mason,
Secretary.

[FR Doc. 90-2189 Filed 1-30-90; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-293]

Certain Crystalline Cefadroxil Monohydrate; Decision to Review Certain Portions of an Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review certain portions of an initial determination (D) issued on December 15, 1989, by the presiding administrative law judge (ALJ) in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Marc A. Bernstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202-252-1087.

SUPPLEMENTARY INFORMATION: On February 1, 1989, Bristol-Myers Company (since renamed Bristol-Myers Squibb Company) (Bristol) filed a complaint with the Commission alleging violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation and sale of certain crystalline cefadroxil monohydrate.

The complaint alleged infringement of claim 1 of U.S. Letters Patent 4,504,657 owned by Bristol. The Commission instituted an investigation into the allegations of Bristol's complaint and published a notice of investigation in the *Federal Register*, 54 FR 10740 (March 15, 1989).

On December 15, 1989, the ALJ issued an ID finding no violations of section 337 in the investigation. Petitions for review of the ID were filed by Bristol, the Commission investigative attorney (IA), and respondents Gema, S.A., Kalipharma, Inc., Purepac Pharmaceutical Co., Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A., and Institut Biochimique, S.A. Responses were filed by all parties that had filed petitions and by respondent Biocraft Laboratories, Inc. No government agency comments were received.

Having examined the record in the investigation, including the ID, the Commission has determined to review the ID's findings and conclusions concerning obviousness and ancillary issues. Such review encompasses the portion of the ID beginning at page 14, with the heading "Seeding," and ending at page 68, above the heading "Infringement." The Commission has determined not to review the remainder of the ID. The Commission has, however, determined, to strike the first two sentences of the final paragraph on page 11 of the ID. The final two sentences of that paragraph are to be inserted at the end of the first paragraph on page 12.

The Commission has determined that the parties' petitions for review and responses thereto have fully addressed the issues to be reviewed. Accordingly, the Commission does not request further briefing on these issues.

In connection with final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) a cease and desist order that could result in a respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon that public interest. The factors that the Commission will consider include the effect that an exclusion order and/or cease and desist order have on (1) the public health and welfare, (2)

competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation, interested government agencies, and any other persons are encouraged to file written submissions on remedy, the public interest, and bonding. Bristol and the IA are also requested to submit a proposed exclusion order and/or proposed cease and desist order(s) for the Commission's consideration. Written submissions, including any proposed orders, must be filed by February 14, 1990, and reply submissions must be filed by February 21, 1990.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

ADDITIONAL INFORMATION: Copies of nonconfidential versions of the ID and all documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-252-1000. Hearing-impaired persons are

advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810.

By order of the Commission.

Issued: January 25, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90-2188 Filed 1-30-90; 8:45 am]

BILLING CODE 7020-02-M

[332-287]

International Agreements to Protect the Environment and Wildlife

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

EFFECTIVE DATE: January 19, 1990.

FOR FURTHER INFORMATION CONTACT: Eugene A. Rosengarden, Director, Office of Tariff Affairs and Trade Agreements, U.S. International Trade Commission, Washington, DC 20436 (telephone 202-252-1592).

BACKGROUND AND SCOPE OF INVESTIGATION:

The Commission instituted investigation No. 332-287, International Agreements to Protect the Environment and Wildlife, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), following receipt of a letter on November 15, 1989, from the Chairman of the Committee on Finance, United States Senate. As requested, the Commission will endeavor to survey international agreements, enforceable through trade sanctions, to protect the environment and wildlife, along with their signatories and significant nonsignatories, dispute settlement and enforcement mechanisms, and procedures for information exchange. In addition, the Commission will identify the administrative and enforcement mechanisms in place within the United States Government and the Government agencies responsible for such activities. Finally, a recommended methodology for future periodic evaluation of the operation of such agreements will be developed. The report will be submitted to the Committee on Finance by January 21, 1991.

PUBLIC HEARING: A public hearing in connection with this investigation will be held in the Hearing Room of the U.S. International Trade Commission, 500 E Street, SW., Washington, DC, on August 15, 1990, at 9:30 a.m. All persons shall have the right to appear by counsel or in person, to present information and to be

heard. Requests to appear at the public hearing should be filed with the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, not later than noon, August 8, 1990. Written prehearing comments (original and 14 copies) should be filed not later than noon, August 9, 1990. Post-hearing comments may be submitted by no later than August 22, 1990.

WRITTEN SUBMISSIONS: Interested parties (including other Federal agencies) are invited to submit written statements concerning the subject of the report. Such statements must be submitted by no later than August 22, 1990, in order to be considered by the Commission. Commercial or financial information that a party desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on 202-252-1809.

By order of the Commission.

Issued: January 25, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90-2191 Filed 1-30-90; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-301]

Certain Imported Breast Prostheses and Manufacturing Processes Therefor; Initial Determination Terminating Respondents on the Basis of Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding officer in the above-captioned investigation terminating the following respondents on the basis of a settlement agreement: Otto Thaemert and Tri-Hawk.

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. §1337). Under the Commission's rules, the presiding officer's initial determination will become the determination of the Commission thirty (30) days after the date of its service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon the parties on January 24, 1990.

Copies of the initial determination, the settlement agreement, and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202-252-1000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810.

WRITTEN COMMENTS: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondents. The original and 14 copies of all such comments must be filed with the Secretary to the Commission, 500 E Street, SW., Washington, DC 20436, no later than 10 days after publication of this notice in the *Federal Register*. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment. Such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why confidential treatment should be granted. The Commission will either accept the submission in confidence or return it.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, telephone 202-252-1802.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, telephone 202-252-1802.

By order of the Commission.

Issued: January 26, 1990.

Kenneth R. Mason,
Secretary.

[FR Doc. 90-2192 Filed 1-30-90; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-290]

Certain Wire Electrical Discharge Machining Apparatus and Components Thereof; Notice of Decision to Review Certain Portions of Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review certain portions of the initial determination (ID) issued on December 7, 1989, by the presiding administrative law judge (ALJ) in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Craig L. McKee, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436; telephone 202-252-1117. Hearing-impaired individuals are advised that information about this matter can be obtained by contacting the Commission's TDD terminal, 202-252-1801.

SUPPLEMENTARY INFORMATION: On January 23, 1989, Elox Corporation (Elox), and A.G. fur Industrielle Elektronik (AGIE), filed a complaint under section 337 of the Tariff Act of 1930 (19 U.S.C. §1337) alleging the importation and sale of certain wire electrical discharge machining apparatus that infringed a U.S. patent, U.S. Letters Patent 3,938,163 (the '163 patent), owned by AGIE, by nine proposed respondents. The Commission instituted an investigation of the complaint and issued a notice of investigation published in the *Federal Register* on March 8, 1989 (54 FR 9906).

On December 7, 1989, the presiding ALJ issued an ID finding a violation of section 337 in this investigation.

Respondents Sodick, Inc., Sodick Co., Ltd., Bridgeport Machines, Inc., KGM Corporation, KGM International Corporation, Yamazen Co., Ltd., and Yamazen U.S.A., Inc. filed a petition for review of the ID, and complainants Elox and AGIE and the Commission investigative attorney filed responses to the petition for review. Comments to the Commission from government agencies were due on January 5, 1990, and none were received.

Having examined the record in this investigation, including the ID, the Commission has determined to review the issues of claim construction, anticipation, obviousness, infringement under the doctrine of equivalents, unenforceability for inequitable conduct, and domestic industry and to not review

the remainder of the ID. The Commission is particularly interested in the following issues:

1. Whether complainants' representations before the Japanese Patent Office concerning Japanese patent application no. 51,406/74 are relevant to and should affect the construction of claim 1 of the '163 patent.

2. Whether the Grodzinsky prior art reference, when construed as a whole, teaches a conical nozzle converging at 13° 24' so as to constitute prior art which prevents claim 1 of the '163 patent from reading on the accused Sodick devices and prevents a finding that the domestic industry, if any, is practicing claim 1 of the '163 patent.

3. (a) Whether complainants' investments in domestic production activities related to the '163 patent are significant when compared to complainants' investments in production facilities abroad related to the patent; (b) whether complainants' investments in domestic production activities related to the '163 patent are significant when compared to complainants' expected U.S. market share for products which exploit the patent; and (c) whether complainants' investment in domestic production activities related to the '163 patent are significant when compared to the investment as a percentage of expected annual sales characteristic of foreign production activities which are related to the '163 patent.

In connection with final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) a cease and desist order that could result in a respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues under review, remedy, the public interest, and bonding. Complainants and the Commission investigative attorney are also requested to submit a proposed exclusion order and/or proposed cease and desist order(s) for the Commission's consideration. Written submissions, including any proposed orders, must be filed by February 7, 1990, and reply submissions must be filed by February 14, 1990.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

ADDITIONAL INFORMATION: Copies of the nonconfidential version of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436; telephone: 202-252-1000.

By order of the Commission.

Issued: January 24, 1990.

Kenneth R. Mason,
Secretary.

[FR Doc. 90-2190 Filed 1-30-90; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Directed Service Order No. 1508-A]

The Atchison, Topeka and Santa Fe Railway Co.—Directed Service—Chicago, Missouri and Western Railway Co., Debtor (Daniel R. Murray, Trustee)¹

AGENCY: Interstate Commerce Commission.

ACTION: Termination of directed service authority.

SUMMARY: Pursuant to 49 U.S.C. 11125, the Commission authorized The Atchison, Topeka and Santa Fe Railway Company (ATSF) to operate as a "Directed Rail Carrier"—uncompensated and without Federal subsidy under 49 U.S.C. 11125(b)(5)—over the Kansas City, MO to Cockrell and East St. Louis, IL lines of the Chicago, Missouri and Western Railway Company (CMW) until February 1, 1990.

By letter dated January 10, 1990, ATSF has notified the Commission that consummation of the sales transactions authorized to CMW Acquisition Corporation (CMWAC) in Finance Docket No. 31567, CMW Acquisition Corp.—Acquisition and Operation Exemption—Lines of the Chicago, Missouri and Western Railway Company Between Kansas City, MO., and Cockrell and East St. Louis, IL., served December 15, 1989, was affected on January 9, 1990, and that ATSF ceased directed service operations on that date. Authority contained in Directed Service Order No. 1508 (DSO 1508) is no longer needed and that order is being vacated.

EFFECTIVE DATE: Directed Service Order No. 1508-A terminating the authority contained in DSO 1508, shall be effective on January 30, 1990.

FOR FURTHER INFORMATION CONTACT:

Melvin F. Clemens, Jr., (202) 275-1559, or Joseph H. Dettmar, (202) 275-7245, (TDD for hearing impaired: (202) 275-1721)

SUPPLEMENTARY INFORMATION: The unsubsidized and uncompensated directed service authority, granted in DSO 1508, was based on a representation by the CMW Trustee that the railroad's cash position would not allow it to continue operations over its entire system, necessitating a cessation of service by CMW over a portion of its lines. To assure continued service to

¹ In Finance Docket No. 31567, served December 15, 1989, the Commission granted authority for CMW Acquisition Corporation to acquire CMW's lines between Kansas City, MO and Cockrell and East St. Louis, IL.

shippers affected by the discontinuance of operations, the Commission in DSO 1508, authorized ATSF to provide interim service over CMW lines between Kansas City, MO, and Cockrell and East St. Louis, IL.

In view of CMWAC's consummation of its purchase of CMW's Kansas City, MO, to Cockrell and East St. Louis, IL lines under its previously granted authority to acquire and operate those lines, the authority contained in DSO 1508 may now be vacated.

This action will not significantly affect either the quality of the human environment or energy conservation.

It is ordered:

1. Directed Service Order No. 1508 is vacated.

2. Notice of this decision shall be given to the general public by publication in the *Federal Register* on January 31, 1990. The decision will also be served on the Federal Railroad Administration; the Association of American Railroads, Transportation Division; American Short Line Railroad Association; ATSF; The Railway Labor Executives' Association, and all parties to Finance Docket No. 31567.

3. This decision and order shall become effective on January 30, 1990.

Decided: January 24, 1990.

By the Commission, Chairman Gradison, Vice Chairman Phillips, Commissioners Simmons, Lamboley and Emmett.

Kathleen M. King,
Acting Secretary.

[FR Doc. 90-2202 Filed 1-30-90; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-23,568]

American Shim Steel Co.; New Kensington, PA; Negative Determination Regarding Application for Reconsideration

By an application dated January 5, 1989, Local #3783 of the United Steelworkers of America (USW) with support from a company official requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on December 18, 1989 and published in the *Federal Register* on January 12, 1990 (55 FR 1291).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

- (1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;
- (2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or
- (3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

It is claimed that imports of hot rolled steel by domestic competitors allowed them to undersell cold rolled steel from the subject firm.

Investigation findings show that American Shim Steel produced cold rolled strip steel from hot rolled steel. The company closed on April 28, 1989.

The Department's denial was based on the fact that the increased import criterion of the Group Eligibility Requirements of the Trade Act of 1974 was not met. U.S. imports of cold rolled strip steel declined absolutely and relative to domestic shipments in 1988 compared to 1987 and in the first four months of 1989 compared to the same period of 1988.

Low-cost imports of the raw material (hot rolled steel) used in the manufacture of the finished article would not form a basis for certification. Under the Trade Act of 1974, only increased imports of articles like or directly competitive with the articles produced by the workers' firm or appropriate subdivision can be considered. Hot rolled steel incorporated into cold rolled strip steel is not like or directly competitive with cold rolled strip steel. This issue was addressed early in the worker adjustment assistance program in *United Shoe Workers of America, AFL/CIO v. Bedell*, 506 F.2d 174, (D.C. Cir. 1974). The court held that imported finished women's shoes were not like or directly competitive with shoe components—shoe counters. Similarly, hot rolled steel incorporated into the finished article (cold rolled strip steel) cannot be considered like or directly competitive with cold rolled strip steel.

Conclusion

After review of the Application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 19th day of January 1990.

Stephen A. Wandner,

Deputy Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 90-2123 Filed 1-30-90; 8:45 am]

BILLING CODE 4510-30-M

Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period January 1990.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-23,523; DeBourgh Manufacturing Co., Steel Fabrication Div., Minneapolis, MN

TA-W-23,545; CRL Components, Fort Dodge, IA

TA-W-23,653; Square D Company, Secaucus, NJ

TA-W-23,655; Teledyne Portland Forge, Portland, IN

TA-W-23,634; Wear-Ever, Chillicothe, OH

TA-W-23,588; Smith Industries—SLI Div., Florham Park, NJ

TA-W-23,629; Reed & Barton Corp., Silversmith Div., Tauton, MA

TA-W-23,602; John Brown E & C, Inc., Casper, WY

TA-W-23,607; Photech, Inc., Williamstown, MA

TA-W-23,590; Union Pacific Resources, Denver, CO

TA-W-23,612; Sims Casting Corp., Syracuse, NY

TA-W-23,611; Security Heel Co., Manchester, NH

TA-W-23,624; Jay Scott Operations Div. of Colt Firearms, Inc., Ellmwood Park, NJ

TA-W-23,628; Quaker Oats Co., Marion, OH

TA-W-23,575; Frank Saltz & Sons Co., Passaic, NJ

TA-W-23,576; Frank Saltz & Sons Co., Wallington, NJ

TA-W-23,626; Plastic Mold Tool & Die, East Rutherford, NJ

TA-W-23,587; Polycast Technology, Hackensack, NJ

TA-W-23,571; C.S.D.C., Branchville, NJ

TA-W-23,608; Republic Hose Manufacturing Corp., Youngstown, OH

TA-W-23,601; The Holoscan Corp., Edison, NJ

TA-W-23,681; Silla Lingerie, Jersey City, NJ

In the following cases, the investigation revealed that the criteria for eligibility has not been met for the reasons specified.

TA-W-23,532; Philips Lighting, Lynn, MA

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,660; Coleman Products Co., Coleman, WI

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,616; Bruce Trucking, Inc., Davis, OK

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,596; Bundy Tubing, Winchester, KY

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,566; Wrangler, Inc., Belmont, MS

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,633; Teknica, Inc., Houston, TX

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,594; B & L Electric Co., Inc., Seminole, OK

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,643; Flushing Shirt Co., Frostburg, MD

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,622; The Home-Stake Royalty Corp., Tulsa, OK

The investigation revealed that criterion (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA-W-23,572; Consolidated Coal Co., Pursglove #15 Mine, Morgantown, WV

U.S. imports of coal are negligible

TA-W-23, 614; Williams & Hinton Well Service, Inc., Delhi, LA

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23, 618; Chrysler Corp., Sterling Heights, MI

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 604; New York Bronze Powder Co., Newark, NJ

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 605; New York Bronze Powder Co., Port Elizabeth, NJ

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 595; Braun Baking Co., Pittsburgh, PA

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 593; Air Treads, Inc., Miami, FL

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 679; Reynolds Metal Corp., Bristol Plant, Bristol, VA

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 635; XY Resources, Inc., Ardmore, OK

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23, 608; Refill Filter Co., Perth Amboy, NJ

Increased imports did not contribute importantly to workers separations at the firm.

Affirmative Determinations**TA-W-23, 613; Swenco-Western, Inc., Denver, CO**

A certification was issued covering all workers separated on or after November 3, 1988.

TA-W-23, 573; Dexter Knitting Mills, Inc., Wallington, NJ

A certification was issued covering all workers separated on or after October 24, 1988.

TA-W-23, 623; ITT Corp., SWF Auto Electric, Fayette, MS

A certification was issued covering all workers separated on or after November 8, 1988.

TA-W-23, 617; C.F. Industries, Inc., Terre Haute, IN

A certification was issued covering all workers separated on or after September 2, 1989 and before December 31, 1989.

TA-W-23, 636; A.O. Smith Electric Products Co., Upper Sandusky, OH

A certification was issued covering all workers separated on or after November 11, 1988.

TA-W-23, 658; Villager, Inc. Philadelphia, PA

A certification was issued covering all workers separated on or after October 16, 1988.

TA-W-23, 620; F. Schumacher & Co., Midland Park, NJ

A certification was issued covering all workers separated on or after December 1, 1989.

TA-W-23, 645; Harris Smith Drilling Co., Ardmore, OK

A certification was issued covering all workers separated on or after November 9, 1988.

TA-W-23, 592; Accuride Corp., Henderson, KY

A certification was issued covering all workers separated on or after November 2, 1988.

TA-W-23, 603; Lindell Drop Forge Co., Lansing, MI

A certification was issued covering all workers separated on or after October 20, 1988.

TA-W-23, 579; Hercules, Inc., Covington, VA

A certification was issued covering all workers separated on or after October 24, 1988.

TA-W-23, 619; Eaton Corp., Fluid Power Div., Power Steering Pump Line, Marshall, MI

A certification was issued covering all workers separated on or after

TA-W-23, 610; The Ridge Co., Forks, WA

A certification was issued covering all workers separated on or after September 1, 1989 and before January 5, 1990.

TA-W-23, 518; Airfoil Textron, Inc., Lima, OH

A certification was issued covering all workers separated on or after October 5, 1988.

TA-W-23, 656; Trico Products Corp., Buffalo, NY

A certification was issued covering all workers separated on or after September 17, 1989.

TA-W-23, 529; Leacock & Co., Inc., Washington, NJ

A certification was issued covering all workers separated on or after October 12, 1988 and before October 24, 1989.

TA-W-23, 642; Eltee Pulsitron, Inc., West Caldwell, NJ

A certification was issued covering all workers separated on or after October 27, 1988.

TA-W-23, 621; Foamex Div., Corry, PA

A certification was issued covering all workers separated on or after October 20, 1988.

TA-W-23, 640; Digicon Geophysical Corp., Oklahoma City, OK

A certification was issued covering all workers separated on or after January 1, 1989.

TA-W-23, 640A; Digicon Geophysical Corp., Denver, CO

A certification was issued covering all workers separated on or after January 1, 1989.

TA-W-23, 649; Microwave Products of America, Sioux Falls, SD

A certification was issued covering all workers separated on or after October 26, 1988.

TA-W-23, 650; Microwave Products of America, Memphis, TN

A certification was issued covering all workers separated on or after October 26, 1988.

TA-W-23, 627; Pleasant Dress Co., Lowell, MA

A certification was issued covering all workers separated on or after October 31, 1988.

TA-W-23, 631; Skaff Manufacturing Co., Lowell, MA

A certification was issued covering all workers separated on or after October 31, 1988.

TA-W-23, 598; Etonic-Tretoen, Inc., Belfast, ME

A certification was issued covering all workers separated on or after October 13, 1988.

TA-W-23, 693; Etonic-Tretoen, Inc., Auburn, ME

A certification was issued covering all workers separated on or after October 13, 1988.

TA-W-23, 501; Oxy Oil & Gas USA, Inc., Tulsa, OK

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 501A; Oxy Oil & Gas USA, Inc., Oklahoma City, OK

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 501B; Oxy Oil & Gas USA, Inc., Houston, TX

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502; Oxy Oil & Gas USA, Inc., Oklahoma City, OK

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502A; Oxy Oil & Gas USA, Inc., AR (North Only)

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502B; Oxy Oil & Gas USA, Inc., Colorado (Excluding Southwest)

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502C; Oxy Oil & Gas USA, Inc., District of Columbia

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502D; Oxy Oil & Gas USA, Inc., Kansas

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502E; Oxy Oil & Gas USA, Inc., Kentucky

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502F; Oxy Oil & Gas USA, Inc., Nebraska

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502G; Oxy Oil & Gas USA, Inc., North Dakota

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 502H; Oxy Oil & Gas USA, Inc., Oklahoma (Excluding Oklahoma City, OK)

A certification was issued covering all workers separated on or after October 6, 1988.

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23,502I; *Oxy Oil & Gas USA, Inc., Texas (North Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23,502J; *Oxy Oil & Gas USA, Inc., West Virginia*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23,502K; *Oxy Oil & Gas USA, Inc., Wyoming*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23,503; *Oxy Oil & Gas USA, Inc., Midland, TX*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 503A; *Oxy Oil & Gas USA, Inc., Colorado (Southwest Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 503B; *Oxy Oil & Gas USA, Inc., New Mexico*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 503C; *Oxy Oil & Gas USA, Inc., Texas (West Only) (Excluding Midland)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 504; *Oxy Oil & Gas USA, Inc., Houston, TX*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 504A; *Oxy Oil & Gas USA, Inc., Louisiana (South Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 540B; *Oxy Oil & Gas USA, Inc., Texas (South Only) (Excluding Houston)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 505; *Oxy Oil & Gas USA, Inc., Jackson, MS*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 505A; *Oxy Oil & Gas USA, Inc., Arkansas (South Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 505B; *Oxy Oil & Gas USA, Inc., Louisiana (North Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 505C; *Oxy Oil & Gas USA, Inc., Mississippi (Excluding Jackson)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 505D; *Oxy Oil & Gas USA, Inc., Texas (East Only)*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 506; *Oxy Oil & Gas USA Inc., Bakerfield, CA*

A certification was issued covering all workers separated on or after October 6, 1988.

TA-W-23, 506A; *Oxy Oil & Gas USA Inc., At Various Other Locations In The State of California*

A certification was issued covering all workers separated on or after October 6, 1988.

I hereby certify that the aforementioned determinations were issued during the month of January 1990. Copies of these determinations are available for inspection in Room 6434, U.S. Department of Labor, 601 D Street NW., Washington, DC 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated January 23, 1990.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance

[FR Doc. 90-2121 Filed 1-30-90; 8:45 am]

BILLING CODE 4510-30-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 12, 1990.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 12, 1990.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, DC 20213.

Signed at Washington, DC this 16th day of January 1990.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Articles produced
A.O. Smith Automotive Products Co. (Workers)	Milan, TN	1/16/90	12/19/89	23,830	Axle Assemblies
AT&T (Workers)	Marlton, NJ	1/16/90	1/3/90	23,831	Telephone Systems
American Cyanamid Co. (ICWU)	Marietta, OH	1/16/90	12/5/89	23,832	Dyes
American Fashions, Inc. (ILGWU)	W. New York, NJ	1/16/90	12/1/89	23,833	Ladies' Coats
Bethlehem Steel Corp. (Workers)	Johnstown, PA	1/16/90	1/4/90	23,834	Steel Rods
Chem Frac, Inc. (Workers)	Ada, OK	1/16/90	12/27/89	23,835	Oil
Christenson Bros. Shake Inc. (Company)	Mt. Vernon, WA	1/16/90	1/4/90	23,836	Cedar Shakes & Shingles
Clifford Industries, Inc. (Workers)	Winfield, AL	1/16/90	12/18/89	23,837	Military Trousers
Del Sportswear, Inc. (Workers)	Tobyhanna, PA	1/16/90	12/30/89	23,838	Women's Blouses
Digital Appliance Controls, Inc.	Elgin, IL	1/16/90	12/22/89	23,839	Controls for Washers & Dryers
Flow Laboratories, Inc. (Workers)	Dublin, VA	1/16/90	1/2/90	23,840	Liquid & Powdered Media
Gordon & Ferguson of Delaware (ACTWU)	Plymouth, MN	1/16/90	12/28/89	23,841	Men's and Boys' Coats

APPENDIX—Continued

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Articles produced
Gordon & Ferguson of Delaware (ACTWU)	Bruce, WI	1/16/90	12/28/89	23,842	Men's and Boys' Coats
Heath Co. (USWA)	St. Joseph, MI	1/16/90	12/11/89	23,843	Computers
Hollywood Shake Co. Inc. (Workers)	Forks, WA	1/16/90	12/11/89	23,844	Shakes & Shingles
Jacques de Loux, Inc. (Workers)	Sellersville, PA	1/16/90	12/21/89	23,845	Men's and Women's Sweaters
Kessler Shoe Mfg. Co., Inc. (Company)	Westminster, MD	1/16/90	12/12/89	23,846	Children's Shoes
Leviton Mfg. Co. (IBEW)	Warwick, RI	1/16/90	1/4/90	23,847	Electrical Wiring Devices
Lincoln Lace & Braid Co. (Company)	Providence, RI	1/16/90	12/13/89	23,848	Shoe Laces
M.D.A. Fashion, Inc. (ILGWU)	Jersey City, NJ	1/16/90	12/1/89	23,849	Women's Coats
Maas & Waldstein Co. (OCAW)	Newark, NJ	1/16/90	12/13/89	23,850	Paints, Laquers & Nail Polish
Mel Coat (ILGWU)	Weehawken, NJ	1/16/90	12/1/89	23,851	Coats & Suits
Miniscribe Corp. (Company)	Longmont, CO	1/16/90	1/5/90	23,852	Disk Drives
Mona Lisa Coat Co. (ILGWU)	Hoboken, NJ	1/16/90	12/1/89	23,853	Ladies' Coats
NWL Controls Systems (UAW)	Kalamazoo, MI	1/16/90	12/11/89	23,854	Hydraulic Controls
R&C Drilling, Inc. (Workers)	Woodward, OK	1/16/90	1/5/90	23,855	Oil & Gas
Rutledge & Salmon, Inc. (Workers)	Chickasha, OK	1/16/90	12/18/89	23,856	Oilfield Drilling
SGS-Thomson Micro-electronic Corp. (Company)	Montgomeryville, PA	1/16/90	11/30/89	23,857	Power Transistors
SGS-Thomson Micro-electronic Corp. (Company)	Somerset, NJ	1/16/90	11/30/89	23,858	Power Transistors
Savion International Inc. (Company)	New York, NY	1/16/90	1/5/90	23,859	Knit Dresses
Sharon Mfg. Co. (UAW)	Lambertville, MI	1/16/90	1/8/90	23,860	Fuel Rails for Autos
Stranco Marine Towing, Inc. (Workers)	Morgan City, LA	1/16/90	11/20/89	23,861	Oil & Gas
Twenty First Century Casting Corp. (Workers)	Mexico, MO	1/16/90	12/29/89	23,862	Mirror Bracket
UNR Home Products (ACTWU)	Paris, IL	1/16/90	1/4/90	23,863	Steel Sinks
Venus Fashions, Inc. (ILGWU)	Hoboken, NJ	1/16/90	12/1/89	23,864	Ladies' Coats
Vinisa Fashions, Inc. (ILGWU)	Hoboken, NJ	1/16/90	12/1/89	23,865	Ladies' Coats
Western Kansas Drilling (Workers)	Hays, KS	1/08/90	12/26/89	23,866	Oil & Gas
Wool Fashions, Inc. (ILGWU)	Hoboken, NJ	1/16/90	12/1/89	23,867	Ladies' Coats

[FR Doc. 90-2122 Filed 1-30-90; 8:45 am]

BILLING CODE 4510-30-M

MARINE MAMMAL COMMISSION**Availability of Draft Guidelines to Govern the Take of Marine Mammals Incidental to Commercial Fishing Operations After 1 October 1993****AGENCY:** Marine Mammal Commission.**ACTION:** Notice of availability and request for comment.

SUMMARY: The 1988 amendments to the Marine Mammal Protection Act direct the Marine Mammal Commission, in consultation with its Committee of Scientific Advisors, to develop and provide recommended Guidelines to the Secretary of Commerce to govern the incidental taking of marine mammals in the course of commercial fishing operations after 1 October 1993. The Commission has developed draft guidelines and is seeking public comment.

DATES: Written comments must be received on or before February 23, 1990.

ADDRESSES: Comments on the draft guidelines should be sent to the Marine Mammal Commission, 1625 I Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Robert J. Hofman, Ph.D., Scientific

Program Director. Telephone: (202) 653-6237.

SUPPLEMENTARY INFORMATION:**Background**

The 1988 amendments to the Marine Mammal Protection Act established a five-year, interim exemption from the Act's moratorium on taking to govern the taking of marine mammals incidental to commercial fishing operations. Those amendments also direct the Marine Mammal Commission, in consultation with its Committee of Scientific Advisors on Marine Mammals, to develop and provide recommended Guidelines to the Secretary of Commerce to govern the incidental taking of marine mammals in the course of commercial fishing operations (other than those subject to section 104(h)(2) of the Marine Mammal Protection Act) after 1 October 1993. In response, the Commission, in consultation with its Committee of Scientific Advisors, has developed and is seeking comments on draft Guidelines.

Copies of the draft Guidelines can be obtained from the Commission at the above address or by calling the Commission at (202) 653-6237.

Summary Findings and Conclusions

In brief, the draft Guidelines conclude that it would be consistent with sound policies of resource management and in

furtherance of the purposes and policies of the Marine Mammal Protection Act to:

1. Reaffirm the Marine Mammal Protection Act goal that the incidental kill and serious injury of marine mammals permitted in the course of commercial fishing operations should be reduced to insignificant levels approaching a zero mortality and serious injury rates;
2. Reinstate the General Permit and "small take" provisions of the Marine Mammal Protection Act to provide the means for assessing the possible effects and for authorizing the incidental take of marine mammals during the course of commercial fishing operations when the available data and ongoing or planned monitoring and enforcement programs are sufficient to reasonably conclude that: (a) The affected species or population stock is within its optimum sustainable range; (b) the authorized level of incidental take will not cause the affected species or population stock to be reduced below its optimum sustainable level or is so small that the effects are negligible and can be ignored; and (c) the authorized level of take will not be exceeded and any unforeseen effects of the incidental take will be detected in time to prevent the affected species or population stock from being reduced below its maximum net productivity level;

3. Amend the Marine Mammal Protection Act to allow the Secretaries of Interior and Commerce to:

a. Authorize the incidental taking of marine mammals listed as endangered or threatened under the Endangered Species Act when: (i) A recovery plan, including an implementation plan, has been developed and adopted by the Department of Commerce or Interior, as appropriate; (ii) there is good reason to believe that the authorized level of take, by itself and in combination with other non-natural and natural mortality, would not cause or contribute to a further reduction in population size or have other than a negligible effect on the time it will take for the affected species or population to rebuild to its maximum net productivity level; and (iii) ongoing and planning monitoring and enforcement programs are adequate to insure that the authorized levels of take are not exceeded and there are no unforeseen effects on the size or productivity of the affected species or population;

b. Authorize the incidental take of marine mammal species and population stocks listed as depleted under the Marine Mammal Protection Act when (i) a conservation plan, including an implementation plan, has been developed and adopted by the Department of Commerce or Interior, as appropriate, to guide recovery efforts, and (ii) the authorized level of take will not cause or contribute to further population declines, or have other than a negligible effect on the time it will take for the affected species or population stock to rebuild to its maximum net productivity level; and

c. Authorize on an experimental basis, for periods of one to three years, the incidental take of species and population stocks whose status is uncertain when (i) the authorized level of incidental take clearly would have a negligible effect on population size and productivity, and (ii) there is reason to believe that ongoing or planned assessment, monitoring, and enforcement programs would be sufficient to insure that the authorized level of take will not be exceeded, the status of the affected species or population stock will be determined with reasonable certainty within one to three years, and possible means for avoiding or reducing the incidental take will be identified and evaluated;

4. Give the National Marine Fisheries Service explicit authority to place observers aboard representative subsets of all commercial fishing vessels operating in U.S. waters; and

5. Direct the National Marine Fisheries Service and the Fish and Wildlife Service, as appropriate, to:

a. Continue the vessel registration, reporting, and observer programs initiated in 1989 to give effect to the 1988 Marine Mammal Protection Act amendments;

b. Hold a workshop or a series of workshops in 1991 to assess and determine what, if any, additional information will be needed to make status-of-stocks and other determinations which will be required to authorize incidental taking of marine mammals during the course of commercial fishing operations in U.S. waters after 1 October 1993;

c. Hold a workshop or series of workshops in 1991 and/or 1992 to identify and evaluate procedures that can be used to assess interactions between marine mammals and fisheries and to develop Fishery Management Plans so as to insure that such interactions do not disadvantage marine mammals; and

d. Promulgate regulations requiring Fishery Management Councils to assess and take into account the food requirements of marine mammals (and uncertainties related thereto) when defining overfishing and calculating the optimal yield of fishery resources.

Dated: January 26, 1990.

John R. Twiss, Jr.,

Executive Director.

[FR Doc. 90-2234 Filed 1-30-90; 8:45 am]

BILLING CODE 6820-31-M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC-17321; (811-3772)]

Arizona Tax Free Fund, Inc.; Application

January 23, 1990.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "1940 Act").

APPLICANT: Arizona Tax Free Fund, Inc.

RELEVANT 1940 ACT SECTION: Section 8(f) and Rule 8f-1 thereunder.

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application on Form N-8F was filed on December 11, 1989.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a

hearing by writing to the SEC's Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 20, 1990, and should be accompanied by proof of service on the Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549; Applicant, 8991 Camelback Road, suite B-302, Scottsdale, AZ 85251.

FOR FURTHER INFORMATION CONTACT: Brion R. Thompson, Special Counsel (202) 272-3016 [Office of Investment Company Regulation].

SUPPLEMENTARY INFORMATION: The following is a summary of the application: the complete application is available for a fee from the SEC's Public Reference Branch in person, or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. On June 20, 1983, Applicant filed Form N-8A to register under the 1940 Act as an open-end, diversified management investment company. On June 20, 1983, Applicant also filed Form N-1A under the Securities Act of 1933, which registration statement became effective on or about October 20, 1983. Thereafter, Applicant began the initial public offering of its shares.

2. At a special meeting on August 4, 1989, Applicant's board of directors approved an agreement and plan of acquisition ("Agreement") providing for the merger of Applicant into Flagship Arizona Double Tax Exempt Fund ("Flagship Fund"), a separate series of Flagship Tax Exempt Funds Trust, a Massachusetts business trust and registered investment company under the 1940 Act (File No. 811-4263). Definitive copies of the Agreement and proxy statement on Form N-14 were filed with the SEC on October 18, 1989, and were mailed to Applicant's shareholders entitled to notice of and to vote on the merger. A majority of Applicant's shareholders approved the Agreement at a special meeting of Applicant's shareholders on November 17, 1989.

3. On November 30, 1989, Applicant had 359,600.952 shares outstanding having a total aggregate net asset value of \$1,878,427.69 and a per share value of

\$5.22. Under the Agreement, on December 1, 1989, all of Applicant's assets and liabilities were transferred to the Flagship Fund in exchange for shares of the Flagship Fund having an aggregate net asset value equal to the aggregate net asset value of Applicant's shares. Applicant then distributed those shares of the Flagship Fund received to its shareholders of record on the closing date of the merger.

4. All proxy solicitation and general administration expenses were borne by Sea Investment Management, Inc., and legal expenses were borne by Flagship Financial, Inc.

5. Applicant has no shareholders and no assets. Applicant is not a party to any litigation or administrative proceeding. Applicant is not engaged, nor does it propose to engage in any business activities other than those necessary to wind up its affairs. Applicant intends to dissolve under Arizona law.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 90-2196 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC-17322; File No. 812-7445]

Canada Life Insurance Company of New York, et al.

January 24, 1990.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1990 (the "1940 Act").

APPLICANTS: Canada Life Insurance Company of New York ("Canada Life"), Canada Life Insurance Company of New York Variable Annuity Account I ("Variable Account"), and Canada Life of America Financial Services, Inc. ("CLAFS") (collectively, "Applicants").

RELEVANT 1940 ACT SECTIONS: Exemption requested under section 6(c) of the 1940 Act from section 26(a)(2)(C) and 27(c)(2).

SUMMARY OF APPLICATION: Applicants seek an order to permit the assessment of a 1.25% charge from the assets of the Variable Account for mortality and expense risks.

FILING DATE: December 19, 1989.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this

application or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on February 20, 1990. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, in the case of an attorney-at-law, by certificate. Request notifications of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549. Applicants, Canada Life Insurance Company of New York, 2 Overhill Road, Scarsdale, New York 10583.

FOR FURTHER INFORMATION CONTACT: Michael V. Wible, Staff Attorney, at (202) 272-2028, or Clifford E. Kirsch, Assistant Director, at (202) 272-2060 (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 253-4300).

Applicants' Representations and Statements:

1. Canada Life is a stock life insurance company incorporated under the laws of the State of New York and is principally engaged in the sale and reinsurance of annuity policies in the State of New York. Canada Life is a wholly owned subsidiary of The Canada Life Assurance Company, a Canadian life insurance company.

2. The Variable Account, registered as a unit investment trust under the 1940 Act, was established in connection with the proposed issuance of flexible premium variable deferred annuity contracts ("Policies") in the State of New York.

3. The Variable Account will invest in shares of the Canada Life of America Series Fund, Inc. ("Series Fund"). The Series Fund is an open-end, diversified management investment company with a number of series, or portfolios. The Variable Account will have a number of subaccounts, each of which will invest solely in a specific corresponding portfolio of the Series Fund.

4. CLAFS will serve as the distributor and principal underwriter of the Policies. CLAFS is registered under the Securities Exchange Act of 1934 as a broker-dealer and is a member of the National Association of Securities Dealers, Inc.

5. The Policies are individual flexible premium variable deferred annuity contracts. The policy owner can allocate net premium payments to one or more subaccounts of the Variable Account, each of which will invest in a corresponding portfolio of the Series Fund. A policy owner also may allocate net premium payments to Canada Life's general account.

6. The application, through incorporation by reference of the registration statement, states that a contingent deferred sales charge of 6% of current premiums is imposed on certain full surrenders or partial withdrawals of policy value to cover expenses relating to registered representatives and other promotional expenses.

7. Canada Life will deduct an administrative fee of \$30 per policy year (\$45 if an agreement for additional premiums to be automatically withdrawn monthly from the policy owner's bank account was in force at any time during the policy year.) This fee will be deducted from the policy value at the end of each policy year prior to the annuity date to compensate Canada Life for the administrative services provided to policy owners. This fee is guaranteed not to increase for the duration of the Policy.

8. Canada Life imposes a charge to compensate it for bearing certain mortality and expense risks under the Policies. This charge is equal to an effective annual rate of 1.25% of the value of the net assets of the Variable Account. Of that amount, approximately 0.40% is attributable to mortality risks, and approximately 0.85% is attributable to expense risks. Canada Life guarantees that this charge will never increase. The mortality risk borne by Canada Life arises from its obligation to make annuity payments regardless of how long all annuitants may live and from its obligation to pay a death benefit that may be higher than the policy value. The expense risk assumed by Canada Life is that the deductions for administrative fees under the Policies may be insufficient to cover the actual future costs incurred by Canada Life.

9. Applicants request exemption from sections 26(a)(2)(C) and 27(c)(2) of the Act to the extent necessary to permit the assessment of the charge for mortality and expense risks against the assets of the Variable Account.

10. Canada Life claims that the mortality and expense risk charge is a reasonable charge to compensate Canada Life for the risk that annuitants under the Policies will live longer as a group than has been anticipated in

setting the annuity rates guaranteed in the Policies; for the risk that the policy value will be less than the death benefit; and for the risk that administrative expenses will be greater than amounts derived from the administrative fee.

11. Canada Life represents that the charge of 1.25% for mortality and expense risk is within the range of industry practice with respect to comparable annuity products. This representation is based upon Canada Life's analysis of publicly available information about similar industry products, taking into consideration such factors as current charge levels, the existence of charge level guarantees, and guaranteed annuity rates. Canada Life will maintain at its administrative offices, available to the Commission, a memorandum setting forth in detail the products analyzed in the course of, and the methodology and results of, its comparative survey.

12. Canada Life does not anticipate that the contingent deferred sales charge will generate sufficient funds to pay the costs of distributing the Policies. If this charge is insufficient to cover the distribution expenses, the deficiency will be met from Canada Life's general account funds, which may include amounts derived from the charge for mortality and expense risks.

13. Canada Life has concluded that there is a reasonable likelihood that the proposed distribution financing arrangements will benefit the Variable Account and the policy owners. The basis for such conclusion is set forth in a memorandum which will be maintained by Canada Life at its administrative offices and will be available to the Commission.

14. Canada Life also represents that the Variable Account will only invest in management investment companies which undertake, in the event such company adopts a plan under Rule 12b-1 to finance distribution expenses, to have a board of directors (or trustees), a majority of whom are not interested persons of the company, formulate and approve any such plan under Rule 12b-1.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 90-2197 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC-17319; File No. 812-7423]

Fidelity Investments Life Insurance Company, et al.

January 23, 1990.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: Fidelity Investments Life Insurance Company ("Fidelity Life"), Fidelity Investments Variable Annuity Account I ("Account"), and Fidelity Brokerage Services, Inc. ("Fidelity Brokerage") (collectively, the "Applicants").

RELEVANT 1940 ACT SECTIONS:

Exemption requested under section 6(c) from section 22(d) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order to permit them to waive in certain circumstances the contingent deferred sales charge applicable under the contract.

FILING DATE: The application was filed on November 7, 1989 and amended on January 12, 1990.

HEARING OR NOTIFICATION OF HEARING:

If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on February 20, 1990. Request a hearing in writing, giving the nature of your interest, the reasons for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicants, 82 Devonshire Street, Boston, Massachusetts 02109. Attention: Rodney R. Rohda, President; and Jeffrey C. Martin, Shea & Gardner, 1800 Massachusetts Avenue NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT:

Michael V. Wible, Staff Attorney, at (202) 272-2026, or Clifford E. Kirsch, Assistant Director, at (202) 272-2060 (Division of Investment Management).

SUPPLEMENTARY INFORMATION:

Following is a summary of the application. The complete application is

available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier at (800) 231-3282 (in Maryland (301) 258-4300).

Applicants' Representations:

1. The Account, registered with the Commission under the 1940 Act as a unit investment trust, is a separate investment account established by Fidelity Life to fund certain variable annuity contracts. The Account consists of seven subaccounts which invest in shares of the Variable Insurance Products Fund and the Variable Insurance Products Fund II, registered open-end management investment companies.

2. The Account funds two types of variable annuity contracts: Fidelity Variable Annuity and Fidelity Retirement Reserves. Fidelity Retirement Reserves is a "combination contract" under which a contract owner may allocate a portion of his or her contract value to the subaccounts of the Account and a portion to a fixed-rate investment option funded through Fidelity Life's general account (Fixed Account). This application involves only the Fidelity Retirement Reserves contract (Contract).

3. Fidelity Life imposes an administrative charge to compensate it for the expenses it incurs administering the contracts. The administrative charge has two components, a daily administrative charge and an annual maintenance charge. The daily administrative charge is assessed by deducting daily from the assets of the subaccounts a percentage of those assets equivalent to an effective annual rate of 0.25%. An annual maintenance charge of \$30 per year is currently assessed, although Fidelity Life reserves the contractual right to increase this charge up to \$50 per year. Moreover, the \$30 per year charge is currently waived prior to the annuity date if the owner's total purchase payments, less any withdrawals, equal at least \$25,000.

4. Fidelity Life does not assess a sales charge under the contract if the owner maintains his or her contract in force for more than five years. However, when a partial or full withdrawal or surrender is made within the first five years of the contract, the amount of purchase payments withdrawn from the owner's contract value (less any amount entitled to a 10% exception) will be subject to a contingent deferred sales charge as follows:

Contract year	Withdrawal charge as percentage of amount of purchase payments withdrawn (%)
1	5
2	4
3	3
4	2
5	1
6 and later	0

5. Applicants submit that it is appropriate in the public interest and consistent with the protection of investors to permit Applicants to waive the contingent deferred sales charge if a contract owner surrenders his or her contract in full within 30 days after he or she is mailed a notice that: (1) The renewal interest rate on any portion of the contract value allocated to the Fixed Account has been decreased by more than 1% from the expiring interest rate; (2) the annual contract maintenance charge for administrative expenses has been increased above the current level being charged when the contract was issued; or (3) the contract maintenance charge has been imposed as a result of a change in practice if that charge previously had been waived for the owner's contract.

6. The Applicants believe that the proposed waiver of the contingent deferred sales charge under the circumstances described in paragraph 5 is fair and provides additional benefits to contract owners. Specifically, each of the three triggering events may make the owner's contract as administered after the triggering event appear less attractive to the owner than the contract appeared prior to the triggering event. The proposed waiver would allow an owner faced with one of the triggering events an opportunity to surrender his or her contract without incurring the contingent deferred sales load. The waiver will be uniformly available to contract owners experiencing the triggering event and will not dilute the interest of any other contract owner.¹

7. Rule 22d-2 exempts registered variable annuity accounts, their principal underwriters, dealers and their sponsoring insurance companies from section 22(d) to the extent necessary to permit variations in the sales load provided that any such variations reflect differences in costs or services, are not unfairly discriminatory, and are described in the prospectus. Applicants do not rely on Rule 22d-2 only because

they do not represent that the proposed waiver reflects differences in sales cost or services.

8. Applicants represent that basic considerations of fairness justify the proposed waiver, and the requested exemptive relief is consistent with the policies and provisions of section 22(d) of the 1940 Act and Rule 22d-1 thereunder.

9. Applicants will revise the registration statement to reflect the proposed waiver of the contract surrender charge. The prospectus will be revised or supplemented to describe the proposed waiver before it is made available and incorporated in new contracts. The waiver will also be available to existing contract owners if and when any of the contingencies triggering the availability of the waiver occur. Existing contract owners will be advised of the proposed waiver within one year of the date when it is first incorporated into new contracts, or earlier if the contingencies which trigger the waiver occur. The proposed waiver of the contract surrender charge will be applied uniformly in a manner consistent with section 22(d) and Rule 22d-1.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 90-2198 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-17323; File No. 812-7378]

General Services Life Insurance Co.; Application for Exemption

DATES: January 25, 1990.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: General Services Life Insurance Company ("General Services Life"), Group Variable Account A and Individual Variable Account B (the "Variable Accounts"), and Federation for Financial Independence ("FFI") (collectively, the "Applicants").

RELEVANT 1940 ACT SECTIONS: Exemption requested under section 6(c) from sections 2(a)(32), 22(c), 27(c)(1) and 27(d) of the Act, and Rules 6e-3(T)(b)(12), 6e-3(T)(b)(13), and 22e-1 thereunder.

SUMMARY OF APPLICATION: Applicants seek an order to permit the previously uncollected portion of the charge made

for premium taxes incurred in connection with the issuance of the policies or certificates to be retained by General Services Life upon surrender or lapse of the policies or certificates.

FILING DATE: The application was filed on August 16, 1989 and amended on January 18, 1990.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on February 20, 1990. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or in the case of an attorney-at-law, by certificate. Request notifications of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549. General Services Life Insurance Company, 2199 South McDowell Extension, Petaluma, California 94954.

FOR FURTHER INFORMATION CONTACT: Staff Attorney Nancy M. Rappa, (202) 272-2622, or Assistant Director Clifford E. Kirsch, (202) 272-2060 (Division of Investment Management, Office of Insurance Products and Legal Compliance).

SUPPLEMENTARY INFORMATION:

Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 321-3282 (in Maryland (301) 253-4300).

Applicants' Representations and Statements

1. General Services Life is a stock life insurance company that was incorporated in the District of Columbia on August 30, 1954 and redomiciled to the State of Iowa in 1988. It is a majority-owned indirect subsidiary of AEGON USA, Inc., an insurance holding company, which is a wholly-owned indirect subsidiary of AEGON, a holding company organized under the laws of the Netherlands and engaged mainly in the insurance and financial services industries.

2. The Variable Accounts were established by General Services Life as separate accounts under the laws of the State of Iowa on May 11, 1989, and are registered with the Commission under

¹ Applicants will amend the application to state that Fidelity Life will absorb sales expenses in situations where the surrender charge is waived as described in paragraph 15 of the application and paragraph 5 of this notice.

the Act as unit investment trusts (File Nos. 33-30523 and 33-30524). The Variable Accounts will invest in shares of one or more management investment companies ("Funds") or series thereof, and each will have a number of investment divisions, each of which invests solely in a specific corresponding series or Fund. The Variable Accounts will invest initially in the Tremont Select Funds (File No. 3-29315).

3. FFI, a registered broker-dealer and a member of the National Association of Securities Dealers, will serve as the principal underwriter of the policies and certificates.

4. Paragraph (b)(13)(iv) of Rule 6e-3(T) provides exemptive relief necessary to permit sales load and administrative expenses or fees to be deducted upon redemption, but does not provide comparable relief for premium tax charges.

5. Accordingly to the application, a charge generally equal to 2.50% of each premium payment will be assessed and, in addition to one other charge, will be collected as part of the "Deferred Policy Loading" in ten equal annual installments starting on the first policy anniversary through the tenth. In the event of a surrender of a policy prior to the tenth policy anniversary after receipt of a premium, an owner will receive his or her surrender value, which is equal to cash value less any debt. The cash value does not include any current Deferred Policy Loading, and the unrecovered Deferred Policy Loading will include a portion of the unrecovered charge for state and local premium taxes.

6. To eliminate any doubt as to full compliance with the Act, Applicants request exemptions from selections 2(a)(32), 22(c), 27(c)(1), and 27(d), and Rules 22c-1, and paragraphs (b)(12) and (b)(13)(iv) of Rule 6e-3(T) thereunder to the extent necessary to permit General Services Life to retain any unrecovered state and local premium tax charge upon a surrender or lapse.

7. Applicants represent that the deferred premium tax charge, which is part of the Deferred Policy Loading as described above, is designed to assist General Services Life in recovering state and local taxes imposed on premiums it receives under the policies. Applicants submit that for several reasons imposition of the charge for premium taxes in the form of a deferred charge is more favorable to owners than a charge that is deducted up front from a premium, which is a more conventional method of imposing this charge. First, the amount of the owner's investment in the Variable Accounts is not

immediately reduced as it is when this charge is deducted up front from a premium. Instead, the full amount of the first policy year and the unrecovered portion of the charge is available for investment in policy years two through ten. Since such amounts will be part of an owner's investment base, deferring the charge may also increase an owner's death benefit. In addition, the total amount charged to any owner is no greater than if this charge is taken in full upon payment of the premium, since the charge is a percentage of the premium actually paid, not current assets.

8. Applicants represent that they do not anticipate making a profit on the deferred premium tax charge. In addition, Applicants represent that the charge is "cost-based" in accordance with Applicant's understanding of the SEC staff's interpretation of sections 26 and 27 and certain exemptions from these provisions in paragraph (b)(13) of Rule 6e-3(T). Applicants also represent that the amount of the charge is the same as it would have been if it were designed as a front-end charge. In particular, this charge does not take into account the time value of money, which would otherwise increase the charge to factor in the investment cost for deferring the charge.

9. As described in the application, Applicants state that granting exemptive relief for the deferred premium tax charge for the reasons described above is supported by relevant SEC precedent. Accordingly,

Applicants request an exemption from sections 2(a)(32), 22(c), 27(c)(1), and 27(d) of the Act and Rule 22c-1 and paragraphs (b)(12) and (b)(13)(iv) of Rule 6e-3(T), to the extent necessary to permit the uncollected portion of the charge for premium taxes to be deducted upon surrender or lapse of the policies in the manner described above.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 90-2193 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

[File No. 1-2402]

Issuer Delisting; Application To Withdraw From Listing and Registration; Geo. A. Hormel & Co., Common Stock, \$2344 Par Value

January 25, 1990.

Geo. A. Hormel & Company ("Company"), has filed an application with the Securities and Exchange Commission ("Commission") pursuant

to section 12(d) of the Securities Exchange Act of 1934 and Rule 12d2-2(d) promulgated thereunder to withdraw the above specified security from listing and registration on the American Stock Exchange, Inc. ("AMEX").

The reasons alleged in the application for withdrawing this security from listing and registration include the following:

The Company's Common stock recently was listed on the New York Stock Exchange ("NYSE"). Trading in the Company's stock on the NYSE commenced on January 16, 1990. In making the decision to withdraw its common stock from listing on the AMEX, the Company considered the direct and indirect costs and expenses attendant to maintaining the dual listing of its common stock on the NYSE and the AMEX. The Company does not see any particular advantage in the dual trading of its stock and believes that dual listing would fragment the market for its common stock.

Any interested person may, on or before February 15, 1990, submit by letter to the Secretary of the Commission, 450 Fifth Street NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchanges and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 90-2131 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-17320; File No. 811-5589]

Nationwide Life Insurance Company, et al.

January 23, 1990.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for an order under the Investment Company Act of 1940 ("1940 Act").

APPLICANTS: Nationwide Life Insurance Company ("Nationwide") Nationwide Ohio DC Variable Account ("Variable

Account"), and Nationwide Financial Services, Inc.

RELEVANT 1940 ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicants seek an order declaring that the Variable Account has ceased to be an investment company.

FILING DATE: The application was filed on June 28, 1989.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any request must be received by the SEC by 5:30 p.m., on February 20, 1990. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send a copy to the Secretary of the SEC along with proof of service by affidavit or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549; Applicants, One Nationwide Plaza, Columbus, Ohio 43216.

FOR FURTHER INFORMATION CONTACT: Joyce M. Pickholz, Staff Attorney, (202) 727-3046 or Heidi Stam, Special Counsel, (202) 727-2060 (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 253-4300).

Applicant's Representations

1. The Variable Account was established by Nationwide on August 3, 1988. On October 7, 1988, Nationwide filed Form N-8A registering the Variable Account as a unit investment trust under the 1940 Act. Concurrently, Nationwide filed a registration statement on Form N-4. The Form N-4 proposed to register an indefinite number of units of a Group Flexible Fund Retirement Variable Annuity Contract (the "Contract") to be issued by the Variable Account. The registration statement never became effective. Applicants have not made a public offering of securities through the Variable Account.

2. Applicants state that the Variable Account is not party to any litigation or administrative proceedings.

3. On May 12, 1989, the Division of Investment Management of the

Commission issued a no-action letter to Nationwide declaring that it would not recommend that the Commission take any enforcement action if Nationwide were to offer the Contract, without registering it under the Securities Act of 1933 ("1933 Act") or the Securities Exchange Act of 1934, or registering the separate account funding the Contract under the 1940 Act (Reference No. IP-5-89). It is Nationwide's position that because the Contract is deemed exempt under section 3(a)(2) of the 1933 Act, the Variable Account is exempt from registration under section 3(c)(11) of the 1940 Act.

For the Commission, by the Division of Investment Management, under the delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 90-2194 Filed 1-30-90; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of reporting requirements submitted for review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such submission.

DATES: Comments should be submitted March 2, 1990. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: William Cline, Small Business Administration, 1441 L Street NW., Room 200, Washington, DC 20416, Telephone: (202) 653-8538.

OMB Reviewer: Gary Waxman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Telephone: (202) 395-7340.

Title: Statement of Personal History.

Form No.: SBA Form 1081.

Frequency: On occasion.

Description of respondents: Non-bank Lending Institutions.

Annual Responses: 300.

Annual Burden Hours: 150.

Title: Portfolio Financing Report.

Form No.: SBA 1031.

Frequency: On occasion.

Description of respondents: Small Business Investment Companies.

Annual Responses: 4,300.

Annual Burden Hours: 1,075.

Title: Liquidation Activities.

Form No.: n/a.

Frequency: On occasion.

Description of respondents: Auctioneer Contractors.

Annual Responses: 3,040.

Annual Burden Hours: 30,400.

Title: Lender Field Visit Report.

Form No.: 1183.

Frequency: On occasion.

Description of respondents: Small Businesses.

Annual Responses: 16,000.

Annual Burden Hours: 16,000.

Title: Loan Servicing Field Visit Report.

Form No.: 712.

Frequency: On occasion.

Description of respondents: Small Businesses.

Annual Responses: 54,000.

Annual Burden Hours: 54,000.

William Cline,

Chief, Administrative, Information Branch.

[FR Doc. 90-2187 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2400]

Florida; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration which made available Individual Assistance, in the form of Disaster Unemployment Assistance, on January 15, 1990, I find that the Counties of Broward, Collier, Dade, Hendry, Lee, Monroe and Palm Beach in the State of Florida constitute a disaster area as a result of damages caused by a severe freeze on December 23 through 25, 1989.

Applications for loans for physical damage may be filed until the close of business on March 16, 1990, and for economic injury until the close of business on October 16, 1990, at the address listed below: Disaster Area 2 Office, Small Business Administration, 120 Ralph McGill Blvd., 14th Floor, Atlanta, GA 30308 or other locally announced locations. In addition, application for economic injury from small businesses located in the

contiguous counties of Charlotte, Glades, and Martin may be filed until the specified date at the above location.

The interest rates are:

For physical damage:

	Percent
Homeowners With Credit Available Elsewhere.....	8.000
Homeowners Without Credit Available Elsewhere.....	4.000
Businesses with Credit Available Elsewhere.....	8.000
Businesses and Non-Profit Organizations Without Credit Available Elsewhere.....	4.000
Others (Including Non-Profit Organizations) With Credit Available Elsewhere.....	9.250
For economic injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere.....	4.000

The number assigned to this disaster for physical damage for the State of Florida is 240007, and for economic injury the number is 692800.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: January 19, 1990.

Alfred E. Judd,

Acting Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 90-2183 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2399]

Texas; Amendment #1; Declaration of Disaster Loan Area

The above-numbered Declaration is hereby amended, in accordance with the notice by the Federal Emergency Management Agency dated January 19, 1990, to include the counties of Dimmit, Kinney, Maverick, Uvalde, and Zavala as a result of damages caused by a severe freeze on December 21 through 24, 1989.

In addition, applications for economic injury from small businesses located in the contiguous counties of Bandera, Edwards, Frio, LaSalle, Medina, Real, Val Verde, and Webb may be filed until the specified date at the above location.

All other information remains the same; i.e., for physical damage, the filing deadline is March 12, 1990, and for economic injury the filing deadline is until the close of business on October 10, 1990.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: January 19, 1990.

Alfred E. Judd,

Acting Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 90-2184 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2401]

Washington; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on January 18, 1990, I find that Lewis County in the State of Washington constitutes a disaster area as a result of damages caused by severe storms and flooding on January 6, 1990. Applications for loans for physical damage may be filed until the close of business on March 19, 1990, and for economic injury until the close of business on October 18, 1990, at the address listed below: Disaster Area 4 Office, Small Business Administration, P.O. Box 13795, Sacramento, CA 95853-4795, or other locally announced locations. In addition, applications for economic injury from small businesses located in the contiguous counties of Cowlitz, Grays Harbor, Pacific, Pierce, Skamania, Thurston, Wahkiakum and Yakima may be filed until the specified date at the above location.

The interest rates are:

	Percent
For physical damage:	
Homeowners With Credit Available Elsewhere.....	8.000
Homeowners Without Credit Available Elsewhere.....	4.000
Businesses With Credit Available Elsewhere.....	8.000
Businesses and Non-Profit Organizations Without Credit Available Elsewhere.....	4.000
Others (including Non-Profit Organizations) With Credit Available Elsewhere.....	9.250
For economic injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere.....	4.000

The number assigned to this disaster for physical damage for the State of Washington is 240106, and for economic injury the number is 695400.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: January 23, 1990.

Bernard Kulik,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 90-2185 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

[License No. 02/02-5532]

Yuzary Capital Funding, Ltd.; Application for License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration (SBA) pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR § 107.102 (1990)) by Yuzary Capital Funding, Ltd., 386 Park Avenue South, Suite 1101, New York, New York 10016, for a license to operate as a small business investment company (SBIC) under the Small Business Investment Act of 1958 (the Act), as amended (15 U.S.C. 661 *et seq.*).

The proposed officers, directors, and shareholders of the Applicant are as follows:

Name	Title
Hiam Yuzary, 2552 East 14th Street, Brooklyn, New York 11235.....	President, Director and sole shareholder.
Frank Segreto, 1430 85th Street, Brooklyn, New York 11228.....	Manager, Director, and Assistant Secretary.
Michael L. Goldman, 49 Emmet Avenue, East Rockaway, New York 11518...	Secretary, Director, and Counsel.

The Applicant, a New York corporation, will begin operations with \$1,005,000 paid-in capital and paid-in surplus. The Applicant will conduct its activities principally in the State of New York, but will consider investments in other areas of the United States.

As an SBIC under section 301(d) of the Act, the Applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Small Business Investment Act of 1958, as amended, from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantage.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operation of the company under their management, including

adequate profitability and financial soundness in accordance with the Small Business Investment Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is further given that any person may, not later than March 2, 1990, submit written comments on the proposed applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street NW., Washington, DC 20416.

A copy of this notice shall be published in a newspaper of general circulation in New York, New York.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: January 22, 1990.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 90-2186 Filed 1-30-90; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Kenosha County, WI

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent to withdraw.

SUMMARY: The FHWA is issuing this notice to advise that an environmental impact statement will not be prepared for the project entitled, "State Trunk Highway (STH) 31, Illinois State Line—STH 50, Kenosha County, Wisconsin." The original notice of intent to prepare an environmental impact statement was issued in the *Federal Register* February 8, 1989.

An Environmental Assessment (EA) was prepared for the project and made available for public review and comment on November 10, 1989. The EA indicates the project will not have significant effects on the quality of the human environment.

FOR FURTHER INFORMATION CONTACT:

Jaclyn Lawton, Environmental Coordinator, Federal Highway Administration, 4502 Vernon Boulevard, Madison, Wisconsin 53705-4905,

Telephone: (608) 264-5967 or FTS 364-5967.

Issued on: January 22, 1990.

Robert W. Cooper,

District Engineer, Madison, Wisconsin.

[FR Doc. 90-2155 Filed 1-30-90; 8:45 am]

BILLING CODE 4910-22-M

National Highway Traffic Safety Administration

[Docket No. 90-01-IP-NO. 1]

Bridgestone (U.S.A.), Inc.; Receipt of Petition for Determination of Inconsequential Noncompliance

Bridgestone (U.S.A.) Inc. (Bridgestone), of Nashville, Tennessee, has petitioned to be exempted from the notification and remedy requirements of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) for an apparent noncompliance with 49 CFR 571.109, Federal Motor Vehicle Safety Standard No. 109, "New Pneumatic Tires," on the basis that it is inconsequential as it relates to motor vehicle safety.

This notice of receipt of a petition is published under Section 157 of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1417) and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Paragraph S4.3.4(b) of Standard No. 109, requires that "Each marking of the tire's maximum load rating pursuant to S4.3(c) in kilograms shall be followed in parenthesis by the equivalent load rating in pounds, rounded to the nearest whole number." During the period October 3, 1989, through December 11, 1989, Bridgestone manufactured and shipped 1,300 tires Model S402BZ, size P175/70R13, which bear the correct labeling information, conforming to all the requirements of FMVSS No. 109 on the outboard side of the tire. The inboard side of the tire also bears all marking required by FMVSS No. 109, however, the parenthetical 1036 PSI should be 1036 LBS as shown below:

"MAX. LOAD 470 kg (1036 PSI)
@ 240 kPa (35 PSI) MAX. PRESS."

The correct marking should be:

"MAX. LOAD 470 kg (1036 LBS)
@ 240 kPa (35 PSI) MAX. PRESS."

Bridgestone supports its petition with the following:

(1) On both sidewalls of the tire, the correct maximum load for the tire is clearly marked in kilograms. The noncomplying information is expressed as a parenthetical to the primary maximum load information.

(2) Completely correct, complying information is clearly labeled on the outboard "face" side of the tire.

(3) The technically noncomplying marking is on the inboard side of the tire.

(4) On both sides of the tire, the correct maximum inflation pressure is clearly marked. Additionally, safety warnings printed on both sidewalls of the tire clearly refer the user to the owner's manual or vehicle placard for correct inflation pressures.

(5) Even when viewed in the most unfavorable light, the technically noncomplying information ("1036 PSI") is at most a nonsequitur [sic] in the context of the "maximum load" line of information.

(6) The technically noncomplying information is inconsequential as it relates to motor vehicle safety because it is impossible to inflate a tire to more than a small fraction of 1036 psi with commercially available inflation equipment.

(7) Most importantly, the technically noncomplying marking will have no effect on the performance or safety of the tire.

Interested persons are invited to submit written data, views and arguments on the petition of Bridgestone, described above. Comments should refer to the Docket Number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street SW., Washington, DC, 20590. It is requested but not required that six copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, the Notice will be published in the *Federal Register* pursuant to the authority indicated below.

Comment closing date: March 2, 1990.

Authority: 15 U.S.C. 1417; delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.

Issued on January 25, 1990.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 90-2175 Filed 1-30-90; 8:45 am]

BILLING CODE 4910-59-M

Sunshine Act Meetings

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 9:31 a.m. on Friday, January 26, 1990, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to consider matters relating to the possible failure of an insured bank.

In calling the meeting, the Board determined, on motion of Director M. Danny Wall (Director of the Office of Thrift Supervision), seconded by Chairman L. William Seidman, concurred in by Mr. Dean S. Marriott, acting in the place and stead of Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: January 26, 1990.

Federal Deposit Insurance Corporation.
Robert E. Feldman,
Deputy Executive Secretary.
[FR Doc. 90-2262 Filed 1-29-90; 4:46 pm]
BILLING CODE 6714-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

January 25, 1990.

TIME AND DATE: 10:00 a.m. Thursday, February 1, 1990.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Dennis Wagner v. Pittston Coal Group, et al.*, Docket No. VA 88-21D. (Issues include whether MSHA and its agents are "persons" under section 105(c) of the Mine Act and are subject to the discriminatory prohibitions of section 105(c).)
2. *Ronald Tolbert v. Chaney Creek Coal Corporation*, Docket No. KENT 86-123-D. (Consideration of a Motion to Reopen.)

Any person intending to attend this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen, (202) 653-5629/(202) 708-9300 for TDD Relay 1-800-877-8339 Toll Free.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 90-2342 Filed 1-29-90; 12:35 pm]

BILLING CODE 6735-01-M

DEPARTMENT OF JUSTICE

United States Parole Commission.

DATE AND TIME: Wednesday, January 31, 1990—9:00 a.m. to 12:00 p.m.

PLACE: 5550 Friendship Blvd., Chevy Chase, Maryland 20815.

STATUS: Closed pursuant to a vote to be taken at the beginning of the meeting.

MATTERS TO BE CONSIDERED: Appeals to the Commission of approximately 17 cases decided by the National Commissioners pursuant to a reference under 28 CFR 2.17. These are all cases originally heard by examiner panels wherein inmates of Federal prisons have applied for parole or are contesting revocation of parole or mandatory release.

CONTACT PERSON FOR MORE INFORMATION:

Jeffrey Kostbar, Case Analyst, National Appeals Board, United States Parole Commission, (301) 492-5968.

Dated: January 18, 1990.

Michael A. Stover,
General Counsel, U.S. Parole Commission.
[FR Doc. 90-2280 Filed 1-29-90; 11:17 am]
BILLING CODE 4410-01-M

DEPARTMENT OF JUSTICE

United States Parole Commission.

DATE AND TIME: Wednesday January 31, 1990, 1:00 p.m., Eastern Standard Time.

PLACE: 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

STATUS: Open—Meeting.

MATTERS TO BE CONSIDERED: The following matters have been placed on the agenda for the open Parole Commission Meeting:

1. Approval of minutes of previous Commission meeting.
2. Reports from the Chairman, Vice Chairman, Commissioners, Legal, Case Operations, Program Coordinator, and Administrative sections.
3. Consideration of proposed modification of 28 CFR 2.62, Transfer Treaty Hearings.
4. Consideration of proposed modification of §§ 2.48-01(d) and 2.13-02(g). Reporter or

Recording Devices used during preliminary hearings.

5. Viewing of Ethics Videotapes.
6. Discussion of Supervision Task Force Report.

7. Discussion of Supervision monitoring and the Hyattsville Project, an intensive supervision program.

8. Consideration of proposed ways the Parole Commission can ease prison crowding.

9. Consideration of proposal to realign regions.

10. Consideration of proposal to equate cocaine addiction with opiate addiction for purposes of computing salient factor scores and the use by the Navy.

11. Proposal to revise the special procedures for rescission cases. (Consent Agenda item)

12. Proposal to delete 28 CFR 2.11(d) and 2.11-03 from the Parole Commission Manual. (Consent Agenda item)

AGENCY CONTACT: Linda Wines Marble, Director, Case Operations and Program Development, United States Parole Commission, (301) 492-5952.

Dated: January 18, 1990.

Michael A. Stover,
General Counsel, U.S. Parole Commission.
[FR Doc. 90-2279 Filed 1-29-90; 11:17 am]
BILLING CODE 4410-01-M

NATIONAL SCIENCE FOUNDATION

DATE AND TIME: February 9, 1990:

8:00 a.m. Closed Session

8:20 a.m. Open Session

PLACE: National Science Foundation, 1800 G Street NW., Room 540, Washington, DC 20550.

STATUS: Most of this meeting will be open to the public. Part of this meeting will be closed to the public.

Matters to be considered February 9:

Closed Session (8:00 a.m. to 8:20 a.m.)

1. Minutes—October Meeting
2. NSB and NSF Staff Nominees
3. Future NSF Budgets
4. Grants and Contracts—Action Item

Open Session (8:20 a.m. to 11:30 a.m.)

5. Chairman's Report
6. Minutes—October Meeting
- Minutes—November Retreat Meeting
7. Director's Report
8. Report on November Executive Committee Retreat
9. Proposed Amendment to Criteria for the Selection of Research Projects by the NSF
10. Guest Speaker: Dr. Lennard Fisk, Associate Administrator for Space Science and Applications of the National Aeronautics and Space Administration
11. Other Business

Thomas Ubois,

Executive Officer.

[FR Doc. 90-2268 Filed 1-29-90; 9:52 am]

BILLING CODE 7555-01-M

Test Report Federal Register

**Wednesday
January 31, 1990**

Part II

Department of Labor

**Occupational Safety and Health
Administration**

29 CFR Part 1910

**Occupational Exposures to Hazardous
Chemicals in Laboratories; Final Rule**

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-150]

RIN 1218-AA00

Occupational Exposures to Hazardous Chemicals in Laboratories

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: By this Notice, the Occupational Safety and Health Administration (OSHA) hereby promulgates a final rule for occupational exposures to hazardous chemicals in laboratories.

The basis for this standard is a determination by the Assistant Secretary, after careful review of the complete rulemaking record, that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals and that a different approach than that found in OSHA's substance specific health standards is warranted to protect workers.

The final standard applies to all laboratories that use hazardous chemicals in accordance with the definition of laboratory use and laboratory scale provided in the standard. Generally, where this standard applies it supersedes the provisions of all other standards in 29 CFR part 1910, subpart Z, except in specific instances identified by this standard. For laboratories covered by this standard, the obligation to maintain employee exposures at or below the permissible exposure limits (PELs) specified in 29 CFR, part 1910, subpart Z is retained. However, the manner in which this obligation is achieved will be determined by each employer through the formulation and implementation of a Chemical Hygiene Plan (CHP). The CHP must include the necessary work practices, procedures and policies to ensure that employees are protected from all potentially hazardous chemicals in use in their work area. Hazardous chemicals as defined by the final standard include not only chemicals regulated in 29 CFR part 1910, subpart Z, but also any chemical meeting the definition of hazardous chemical with respect to health hazards as defined in OSHA's Hazard Communication Standard, 29 CFR 1910.1200(c).

Among other requirements, the final standard provides for employee training

and information, medical consultation and examinations, hazard identification, respirator use and recordkeeping. To the extent possible, the standard allows a large measure of flexibility in compliance methods.

DATES: *Effective Date:* This final standard published today shall become effective on May 1, 1990.

Compliance Date: Employers shall have completed an appropriate Chemical Hygiene Plan and commenced carrying out its provisions by January 31, 1991.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of the standard, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Room N3649, Washington, DC 20210; Telephone: (202) 523-8151.

SUPPLEMENTARY INFORMATION:**Information Collection Requirements**

On March 31, 1983, the Office of Management and Budget (OMB) published a new 5 CFR part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (48 FR 13666). Part 1320, which became effective on April 30, 1983 and was revised on May 10, 1988 (52 FR 16618), sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements. The sections of this final standard on occupational exposures to hazardous chemicals in laboratories which may create recordkeeping requirements are paragraphs (d) Employee Exposure Determination; (e) Chemical Hygiene Plan; (f) Employee Information and Training; (g) Medical Consultations and Medical Examinations; (h) Hazard Identification; and (j) Recordkeeping.

In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA has submitted the information collection requirements for this final standard to OMB for review and has been granted approval of those provisions through 10/31/92. The OMB Control Number is 1218-0131.

Concurrent with granting approval of the information collection requirements for the proposed standard, OMB attached remarks which it requested the Agency to address when submitting the

final rule for review. These remarks are reproduced below, followed by the Agency's response.

Each element of the chemical hygiene plan § 1910.1450(d)(2)(i) through (d)(x), shall be completely justified. This justification shall include a summary of the comments in the public rulemaking record on each element. Second, the final paperwork package shall include an estimate of the burden hours associated with § 1910.134, the respiratory protection program, which is referenced in § 1910.1450(e). Third, the agency shall arrive at a net change in burden by estimating the reduction in burden resulting from the exemption for laboratories from recordkeeping requirements in the general industry health standards. Fourth, the burden estimate of five minutes for exposure evaluations and three hours for development of chemical hygiene plans shall be supported by evidence from the record, or shall be revised accordingly. Fifth, the estimated current compliance rate of 56 percent for the chemical hygiene plan requirements shall be supported by evidence from the record, or shall be revised accordingly.

The Chemical Hygiene Plan has been redesignated as paragraph (e) in the final rule. OSHA believes that it has sufficient justification for the inclusion of each element of the Chemical Hygiene Plan including supporting comments from the public rulemaking record. In many cases, however, the comments addressed the appropriateness of the Chemical Hygiene in general terms rather than addressing individual elements. The discussion of the Chemical Hygiene Plan is presented in part VI of this preamble and includes summarization of comments in the record regarding specific elements of the Plan.

With respect to the burden hours associated with the respiratory program in § 1910.134, OSHA has assumed zero hours since the Laboratory Standard does not itself impose a requirement to use respirators. Paragraph (i) concerning the use of respirators is included to remind employers of the existing compliance obligation of the Respiratory Protection Standard which is found at 29 CFR 1910.134. Burden hours associated with respirator use are addressed in the Respiratory Protection Standard.

Laboratories are exempted in this final rule from the explicit requirements for recordkeeping prescribed in the substance specific General Industry Standards, except where a standard specifically includes laboratories. However, the Laboratory Standard includes in paragraph (d), requirements, under certain conditions, for complying with exposure monitoring of other standards. Similarly, medical

consultation and medical examinations provisions appear in paragraph (g).

Employers are required to establish and maintain for each employee accurate records of any exposure measurements and any medical consultations or examination results performed under this standard. Thus, OSHA's estimate of the burden hours associated with the recordkeeping requirements under the Laboratory Standard does not represent a reduction in burden as a result of exempting laboratories from the recordkeeping provisions of the General Industry Standards.

The burden estimate of five minutes for an exposure evaluation included in the proposed standard is no longer relevant since this requirement has been deleted in the final standard. The burden estimates associated with the development of chemical hygiene plans as presented in the proposed standard have been revised upward for small and medium size laboratories. The proposed standard estimated that 2, 5, and 8 hours, respectively, for small, medium and large laboratories would be required to develop chemical hygiene plans. Comments to the record (see e.g. Tr. 80 and Tr. 152) indicated that additional time might be required for chemical hygiene officers to acquaint themselves with proper chemical hygiene. OSHA believes that the additional time is reasonable, particularly for small and medium size laboratories. OSHA has therefore revised its estimate of the burden hours in connection with the development of chemical hygiene plans to eight hours for all laboratories, regardless of size.

OSHA estimates that approximately 67 percent of all laboratories that would be affected by the final standard are currently in compliance with the chemical hygiene plan requirements. This estimate is based on information generated in a survey of potentially affected laboratories conducted by Booz, Allen and Hamilton under contract to the Agency (Ex. 7-11). OSHA received no comments to indicate that the compliance rates for chemical hygiene plans for individual laboratory sectors that were presented in the Preliminary Regulatory Impact Assessment were not accurate estimates.

Public reporting burden for this collection of information is estimated to average, in the first year of compliance, 8 hours per laboratory, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send

comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, Room N-1301, 200 Constitution Avenue NW., Washington, DC 20210; and to the Office of Management and Budget, Paperwork Reduction Project (1218-0131), Washington, DC 20503.

Table of Contents

- I. Pertinent Legal Authority
- II. History of the Regulation
- III. Significance of Risk
- IV. Summary of Regulatory Impact
 - Assessment, Regulatory Flexibility
 - Assessment and Environmental Impact
 - Assessment
- V. Summary of Major Differences Between the Proposed and Final Standard
- VI. Summary of Issues and Explanation of Provisions of the Final Standard
 - Paragraph (a) Scope and Application
 - Preemption by Other OSHA Health Standards
 - Facilities
 - Chemicals
 - Paragraph (b) Definitions
 - Paragraph (c) Permissible exposure limits
 - Paragraph (d) Employee exposure determination
 - Paragraph (e) Chemical hygiene plan
 - Paragraph (f) Information and training
 - Paragraph (g) Medical consultation and medical examination
 - Paragraph (h) Hazard identification
 - Paragraph (i) Use of respirators
 - Paragraph (j) Recordkeeping
 - Paragraph (k) Dates
 - Effective date
 - Start-up date
 - Paragraph (l) Appendices
- VII. Federalism and State Plan Applicability
- VIII. Authority
 - The Standard
 - Appendix A: National Research Council Recommendations Concerning Chemical Hygiene in Laboratories
 - Appendix B: References

I. Pertinent Legal Authority

Authority for issuance of this standard is found primarily in sections 6(b), 8(c), and 8(g)(2) of the OSH Act, 29 U.S.C. 655(b), 657(c), and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as:

[A] Standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

This standard is also issued pursuant to section 6(b)(8) of the Act. This section provides as follows:

Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

For the most part, all of the subpart Z standards will be superseded for laboratories except as noted below. This standard better effectuates the purposes of the Act because it acknowledges the unique characteristics of the laboratory workplace and reflects a more reasonable approach to regulating toxic substances in the laboratory than the approach taken in the General Industry standards in 29 CFR part 1910, Subpart Z. Many of the standards in subpart Z were national consensus standards. This standard does not eliminate the requirement to maintain exposures below the applicable PELs and, therefore, does not reduce worker protection but provides greater flexibility in the methods of achieving it.

Authority to issue this standard is also found in section 8(c) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. Provisions of OSHA standards which require the making and maintenance of records of medical examinations and the like are issued pursuant to section 8(c) of the Act.

The Secretary's authority to issue this standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary to "prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under [the] Act," in this case as part of, or ancillary to, a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1));

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act (29 U.S.C. 651(b)(3));

Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(4));

Providing for the development and promulgation of occupational safety and health standards (29 U.S.C. 651 (b)(9));

Providing for appropriate reporting procedures * * * which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem (29 U.S.C. 651 (b)(12));

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * * (29 U.S.C. 651(b)(6));

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13)); and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (29 U.S.C. 651(b)(5)).

Because the laboratory standard is reasonably related to these statutory goal, the Secretary finds this standard necessary and appropriate to carry out his responsibilities under the Act.

II. Background and History of the Regulation

Since the early eighties, OSHA has been involved in efforts directed toward formulating a special regulatory approach to control occupational exposures to hazardous chemicals in laboratories.

Prior to the promulgation of this final rule, laboratories were subject to all provisions of OSHA's General Industry Standards codified in 29 CFR part 1910, subpart Z. However, interested parties involved in laboratory operations have for some time opposed this arrangement. Through their participation in rulemaking proceedings for certain OSHA health standards, various interest groups have indicated that the Agency's approach to standards development did not result in standards that were relevant to laboratories and were not focused on typical exposure conditions in laboratories. As a result they argued that laboratories were required to comply with provisions that were more appropriately designed for industrial workplaces.

Objections regarding the inappropriateness of applying OSHA's health standards to laboratory operations began to surface in 1973, when OSHA began rulemaking for 14 specified carcinogens (29 CFR 1910.1003-1910.1004, 1910.1006-1910.1018; one standard was subsequently vacated). The preamble to the standard regulating those substances noted the following objections from parties representing laboratories interests: Laboratories use very small amounts of the substances; laboratory work is done by, or under the direct supervision of, highly trained

personnel; and in the absence of an exemption or other special consideration, the standard would obstruct important research, including cancer research (39 FR 3756, 3759, January 29, 1974).

While the final standard (39 FR at 3759) did include some provisions for the laboratory use of these substances (see, for example, 39 FR at 3787, 3790), these provisions were later vacated on procedural grounds. See *Synthetic Organic Chemical Manufacturers Association v. Brennan*, 503 F.2d 1155, 1160 (CA 3, 1974), cert. den. 420 U.S. 973 (1975), reh. den. 423 U.S. 886 (1975). See also *SOCMA v. Brennan*, 506 F.2d 385, 392 (CA 3, 1974, cert. den. 423 U.S. 830 (1975)).

Similar objections were raised by laboratories in response to OSHA's Cancer Policy (45 FR 5001, 5202, January 22, 1980). Again, OSHA considered the concerns expressed by the laboratory community. While laboratories were included under the scope of the Cancer Policy, OSHA reserved the right to revisit the issue and, if warranted, to waive or modify procedures related to laboratories regarding a specific potential occupational carcinogen. (See 45 FR at 5202).

Concerns regarding the impact of the Cancer Policy on laboratory operations prompted the formation of informal groups of laboratory experts to study the problem further. OSHA met with members of one such group, representing a cross section of various types of laboratory disciplines in government, industry and academia. OSHA also met with members of professional organizations representing clinical laboratories. Input received from these groups was carefully considered. As a result, OSHA decided that further investigation into the problems related to occupational exposure to toxic and hazardous substances in laboratories was warranted.

On April 14, 1981, OSHA published a Request for Comment and Information concerning health hazards of toxic substances in laboratories (46 FR 21785). This action was taken to gain further insight into the problems OSHA health standards might pose for laboratories. Interested parties were invited to submit comments, views and data concerning issues which OSHA needed to address in deciding whether a special laboratory policy was necessary. Some 200 comments were received in response to this Notice.

On July 24, 1986, on the basis of information received in response to the Request for Comments and other considerations, OSHA published a notice of proposed rulemaking (NPRM)

entitled "Occupational Exposures to Toxic Substances in Laboratories" (51 FR 26660). OSHA received 129 comments in response to the NPRM.

The NPRM also invited requests for an informal public hearing. Two requests were received: United Steel Workers of America, (Ex. 8-38) and Standard Oil Company (Ex. 8-42).

A public hearing, conducted under OSHA's procedural regulations for rulemaking (29 CFR part 1911), was held from March 24-26, 1987 in Washington, DC. The hearing was presided over by Administrative Law Judge Glenn R. Lawrence. All participants who had filed appropriate Notices of Intent to Appear at the hearing were given the opportunity to present oral testimony and question other witnesses.

The 3-day hearing generated some 400 pages of testimony from a number of interested parties. The post-hearing comment period during which hearing participants were permitted to submit additional data to the record was originally scheduled to close on June 9, 1987. However, in response to a request for additional time by one of the participants (Ex. 37), Judge Lawrence extended the post-hearing period until July 30, 1987. Twenty submissions were received during this period.

The public record for the proposed rule was certified by Judge Lawrence on May 18, 1988. All materials submitted to the OSHA Docket Office, Docket No. H-150, either by OSHA or the public are contained in the record.

Copies of the official list of entries to the record and the exhibits are available from the OSHA Docket Office, Docket No. H-150 Room N-2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; Telephone: (202) 523-7894.

III. Significance of Risk

OSHA included a discussion of significant risk in the preamble to the proposed standard. In that discussion OSHA reviewed the relevance of the Supreme Court's Benzene Decision (*Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980)) to the proposed standard.

In the Benzene decision, the Court said that section 3(8) of the Act applies to all permanent standards promulgated under the Act and requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment.

The "significant risk" determination constitutes a finding that, absent the change in practices mandated by the

standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm. Id. at 642. A significant risk finding, however, does not require mathematical precision or anything approaching scientific certainty if the "best available evidence" does not warrant that degree of proof. Id. at 655-656; 29 U.S.C. 655(b)(5). Rather, the Agency may base its finding largely on policy considerations and has considerable leeway with the kinds of assumptions it applies in interpreting the data supporting it. Id.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the proposed standard, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer a material impairment of health * * * (section 6(b)(5) of the Act). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is 'Id. at 509.

OSHA has begun to develop a systematic approach to significant risk determination. This approach was introduced in the publication of the significant risk determination for arsenic (48 FR 1864, January 14, 1983). OSHA identified, in the arsenic case, five factors that comprised the basis of a significant risk determination. Those factors were relevant to evaluating risks associated with specific substances. This standard, however, concerns risks in the laboratory workplace which could result from a large variety of substances or work conditions. Therefore, OSHA believes the methodology used in the arsenic risk determination may not be fully applicable for this standard.

This is a generic laboratory standard. Laboratories generally have many hazardous chemicals present to which exposures are intermittent rather than a few substances to which there are regular exposures. Therefore the appropriate consideration is whether a significant risk would be present in laboratories without good laboratory practices rather than development and consideration of risk assessments for hundreds of chemicals present, an

exercise likely to be impossible to perform. OSHA's significant risk finding for this standard is based on the following factors: Epidemiological information relating to disease and mortality rates among chemists; evidence from other OSHA rulemaking proceedings which show significant risks for specific substances which are used in the laboratory workplace; the general recognition by the regulated community that safe work practices are necessary to prevent adverse health effects; case report information about adverse health effects resulting from exposures to substances commonly used in laboratories; and relevant policy considerations.

In the absence of safe work practices, exposure to hazardous chemicals in the laboratory presents a significant risk of material health impairment. None of the comments submitted to the record indicates that hazardous chemicals do not pose a risk to laboratory workers. If OSHA's health standards that now apply to laboratories were withdrawn it is clear that the risk would increase. OSHA's intent in this standard is to reduce significant risk by at least as much as current standards do, while regulating in a manner more appropriate to laboratories. Because the working conditions and exposures are of a different nature than those in general industry, the hazards should be regulated in a different way.

The fact that many laboratory employers have implemented some type of work practices to control employee exposure to hazardous chemicals in general and carcinogens in particular, indicates the recognition of a potentially unsafe work environment. Many corporations, academic institutions and government agencies have devised detailed guidelines for the handling of hazardous chemicals (see, for example, Exs. 3-2, 3-50, 3-77 and 7-1). In particular, they have given carcinogens and suspected carcinogens special treatment.

In the preamble to the proposed standard (51 FR at 26665), OSHA noted that several commenters who have active safety and health programs (see, for example, Exs. 3-79, 3-85, and 3-108) indicated that their records show the absence of risk in their laboratory operations. OSHA believes that these records really attest to the effectiveness of programs such as the Chemical Hygiene Plan required by this final rule in reducing the risks due to inherent hazards associated with laboratory work (see Exs. 3-29, 3-64, 3-145 and 3-174). In contrast, OSHA also notes the comments of organizations without

similar safety and health programs (see Exs. 3-35, 3-36 and 3-133). These comments indicate that there may be significant risks associated with chemicals to which laboratory personnel are exposed.

The preamble to the proposed standard cited five studies on the long-term effects of exposure to toxic substances in the laboratory (51 FR at 26665). A study by Li et al. (Ex. 7-3), "Cancer Mortality Among Chemists," was based on data from 3,637 members of the American Chemical Society who died between 1948 and 1967. Li found a significantly higher proportion of deaths from cancer among male chemists ages 20-64, and age 64 and older, as compared to professional men in general. Li stated: "Though not conclusive, [the study] raises the possibility that occupational exposure of chemists increases their risk of lymphoma and pancreatic cancer."

Robert Olin, of the Royal School of Technology, Stockholm, has done several studies of disease and mortality among Swedish chemists. In a 1976 study (Ex. 7-4), "Leukemia and Hodgkin's Disease Among Swedish Chemistry Graduates," he traced 517 graduates; 58 had died, 22 from cancer, which were nine more than expected. Six cancer deaths were due to malignant lymphomas or leukemias, a significant increase over the 1.7 deaths expected from this cause. Olin noted a somewhat lower than expected incidence of lung cancer. Olin tried to investigate the type and extent of chemical exposure in the cohort by asking a senior professor to distinguish between persons who had done any type of laboratory work ("chemists") and those who had not ("non-chemists"). All but one of the 22 cancer deaths occurred in the "chemist" group and Olin concluded: "[It] strongly suggests that the difference in the neoplasm death rates of the two groups is at least partly attributable to work in chemical laboratories."

Another study by Olin (Ex. 7-5), "The Hazards of a Chemical Laboratory Environment: A Study of the Mortality of Two Cohorts of Swedish Chemists," indicated a tendency toward a lower overall death among chemists, but a higher mortality rate due to tumors. An increase in mortality due to leukemia, malignant lymphomas or urogenital tumors and possibly brain tumors was observed. Olin stated: "It is probable that employment in a chemical laboratory, and particularly in organic chemistry, is associated to some extent with the increase." A follow-up study by Olin published in 1980 revealed similar findings. (Ex. 7-6).

A study by Sheila K. Hoar (Ex. 7-7), "A Retrospective Cohort Study of Mortality and Cancer Incidence Among Chemists," was based on data from employees of the DuPont Company from 1964-1977. This study indicated that male chemists experienced a lower overall mortality rate than other salaried employees at DuPont. Chemists appeared to have a higher risk of death from malignancies of the colon, cerebrovascular disease and a higher incidence of melanoma and prostate cancer than non-chemists. Chemists, however, had a lower rate of lung cancer than non-chemists. Hoar noted that anticipated excesses of certain types of cancer shown in other studies were not observed "possibly because of the use of absolute mortality rates [rather than proportional rates], inadequate length of follow-up, exposure to hazardous chemicals by the referent group, or restriction of case identification to active employees."

The Hoar study indicated, in general, less of a risk associated with working in laboratories than did the other studies. The Hoar study further pointed out that if the results of the other studies, expressed as proportional rates, were adjusted to show standardized mortality rates, apparent differences would be smaller but still present. Another explanation for the difference could be that DuPont followed better laboratory practices than did the laboratories covered by the first three studies.

OSHA believes, based on the known existence of hazardous substances in laboratories, the probability of risk associated with the results of the foregoing studies, and evidence from other OSHA rulemaking proceedings, that there is sufficient evidence of significant risk of material health impairment to workers not protected by an appropriate standard to justify this standard under the OSH Act.

Although OSHA does not believe it is necessary to demonstrate significant risk on a substance by substance basis, it is useful to focus on some of the substances currently regulated by OSHA for which a significant risk determination has been or could be made. The fact that many laboratory workers are exposed to these substances supports the general significant risk showing for laboratories. In the benzene decision, the Supreme Court noted that: "In other proceedings, the Agency has had a good deal of data from animal experiments on which it could base a conclusion on the significance of risk." 448 U.S. at 657, n. 64. The Court then referred to findings in the rulemaking record for vinyl chloride,

and bis chloromethyl ether. An extension of the Court's reasoning indicates that findings for some of the other substances regulated in the 1974 carcinogen standard also form a sufficient basis for a significant risk determination. For example, benzidine was demonstrated to be a carcinogen in experimental animals and, by virtue of epidemiologic investigations, carcinogenic in humans. Epidemiological studies conducted by Melick *et al.* and Koss *et al.* have established the potential of 4-aminodiphenyl to induce bladder cancer in humans.

Recent studies on ethylene oxide indicate significant risk at levels as low as 1 part per million parts of air over a working lifetime. (Final standard for Ethylene Oxide, (49 FR 25734, June 22, 1984).) OSHA has determined that a significant risk of material health impairment exists in the event of overexposure to many of the specific substances it regulates. The fact that many of these substances are also used in laboratories provides a potential for significant risk to laboratory workers.

The preamble to the proposed standard also included case reports as evidence of hazardous chemical exposures in laboratories (51 FR at 26666). In particular, it cited the results of a 1979 survey pertaining to xylene exposures among members of the California Association of Cytotechnologists. (CC) (Ex. 3-41). The problems noted among the 70 respondents to the survey included inadequate ventilation (59%); lack of an exhaust system (22.6%); and lack of inspection of the exhaust system (43%). The comment submitted by the CAC also included an article by Roberta N. Hipolito which documents five case studies of xylene poisoning in laboratory workers. A xylene study of 71 workers in 15 laboratories indicated that there were 170 health complaints among the group. In addition, 45.5% felt that they had experienced significant exposures to xylene and 14% considered changing jobs due to xylene exposure.

Health hazard evaluations conducted by the National Institute for Occupational Safety and Health (NIOSH) present further evidence of the risk associated with hazardous chemicals in laboratory operations. NIOSH was requested on several occasions to evaluate employee exposures to xylene, formaldehyde, chloroform, toluene and methyl methacrylate in histology, cytology and surgical pathology laboratories following employee complaints of respiratory and behavioral problems. The result of these investigations

showed that, in some instances, a health hazard did exist to employees exposed to certain of these substances. Major contributors to the hazardous conditions included ineffective exhaust ventilation and poor work practices (Ex. 7-8).

An article in International Laboratory cites examples of injury from hazardous chemical exposure in the laboratory which range from dermatitis to fatal pulmonary edema. The author, a research chemist with the Centers for Disease Control, U.S. Department of Health and Human Services, explains that these examples demonstrate at least three important points:

First, exposure to toxic agents in the laboratory can have severe consequences, including death; second, these injuries can occur in any type of laboratory where toxic chemicals are handled; and third and most important, most all of the injuries are preventable. If these people had had the proper equipment, if they had been using the proper techniques and if they had had adequate knowledge, these exposures probably would not have occurred. (Ex. 7-9).

During the public hearing on the proposed laboratory standard, Dr. Jay Young, a chemical safety consultant specializing in laboratory safety, cited several examples of risks confronting laboratory workers. Dr. Young's examples were gleaned from the Manufacturing Chemists' Association (MCA) compilation of case histories of accidents or near-accidents occurring in the chemical industry, including those occurring in laboratories. The MCA case histories were based on incidents voluntarily reported by member companies between 1951 and 1977. In presenting particular accident case histories, Dr. Young also stated that provisions prescribed in the proposed standard would have prevented such incidents. For example, regarding MCA Accident Case History No. 238, Dr. Young stated:

A control laboratory analyst was exposed to hydrogen cyanide, an extremely toxic gas, because there was no provision in her operating procedures to protect [against] such exposure. Fortunately, in this instance she recovered after a short hospital stay. Clearly, a [Chemical Hygiene Plan] conforming to the [proposed standard] would have established standard operating procedures that would have mandated the use of engineering controls to prevent a near-fatal exposure. (Tr. 66.)

Dr. Young also presented MCA Accident Case History No. 34:

A carbon monoxide cylinder ruptured causing the death of the laboratory worker who was either connecting or disconnecting the cylinder to a gas line. Probably, the rupture was caused by contamination of high pressure carbon monoxide with air. A CHP

with provisions for suitable chemical safety instruction would have prevented this incident. (Tr. 65.)

Additional evidence supporting the significant risk argument was noted in the testimony of Diane Factor of the AFL-CIO. According to Ms. Factor, her first encounter with health hazards in the laboratory came when she was a chemistry student and part-time laboratory assistant. Ms. Factor said, "As I sat in the stockroom of the laboratory during quiet hours, I would read toxicology texts and was surprised to learn that several of the substances we routinely handled in the lab were extremely toxic." Ms. Factor said that she became particularly interested in the potential exposure to mercury, because of the tendency of beginning chemistry students to break thermometers. The visible evidence of the presence of mercury in areas of the laboratory prompted her to bring the problem to the attention of one of her professors who, subsequently, conducted instrumental monitoring which showed high levels of mercury vapors in the laboratory classrooms and stockroom. Because of her concern for a safe laboratory environment, Ms. Factor said that she was assigned to clean up the labs. As she testified, "In that process, I discovered a laundry list of problems—improper storage of chemicals, as explosive as picric acid, leaking drums, incompatible storage, lab hoods that did not function, incorrect disposal of solvents and metal and friable asbestos." As she stated further: "The correction of these problems was expensive and time consuming but was accepted by the supervision of the department because they realized that I had uncovered a virtual time bomb." (Tr. 460-461).

Ms. Factor, an industrial hygienist, was also previously employed by CAL OSHA as a field inspector for five years, during which time she had many opportunities to inspect various types of laboratories. Ms. Factor also related some of her experiences in inspecting laboratories during her employment at CAL OSHA which included the lack of properly functioning hoods and make-shift laboratories without any ventilation (Tr. 462).

Dr. Daniel Teitelbaum, Director of Medical Toxicology at Denver Clinic Medical Centers also testified regarding the inherent risks associated with laboratory work. He stated:

In my view there are common risks and responsibilities in laboratories, no matter what their mission. The common risks arise from the need to carry out exacting and frequently dangerous procedures at the cutting edge of the laboratory discipline. The

common responsibility requires that the best possible working conditions and safest possible environment is provided in which to carry out the analytical and experimental procedure. Only in this fashion can we assure that the laboratory scientist is not harmed by his or her work. (Tr. 48.)

In addition to the risk posed by exposure to individual hazardous chemicals in the laboratory, workers are often exposed to a mixture of hazardous substances which may produce a variety of toxic reactions. In particular, such reactions may be additive or synergistic. This situation was recognized by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1963 when it adopted its formula to compute exposure to chemical mixtures. OSHA incorporated this formula into its air contaminants standard, 29 CFR 1910.1000(d)(2)(i) in 1971.

Because such mixed exposures may be more common in laboratories than in most other workplaces (see, for example, Exs. 3-27, 3-29, 3-107), possible synergistic effects could pose a greater risk to laboratory workers than the risk posed to workers exposed to the same substances singly.

Based on the factors discussed above, OSHA feels that exposure to hazardous chemicals in laboratories poses a significant risk of material health impairment, in the absence of the safe work practices and other provisions of this standard. Therefore, the provisions of this standard are reasonably necessary to reduce or eliminate that significant risk.

OSHA solicited comment on the arguments it presented regarding risk determination in the proposed standard. Two comments were received.

Thomas Evans, Director of Safety and Environmental Health for Monsanto (Ex. 8-36) concurred with OSHA's position that risk determinations in laboratories must consider the nature of the laboratory work and reflect the variety of materials and operations associated with a typical laboratory.

Standard Oil presented an opposing view:

With respect to the bases for the significant risk finding, Standard Oil believes that (a) the referenced disease and mortality rate studies are non-conclusive, (b) the mere presence of an OSHA regulated chemical substance in the laboratory should not be used to designate or imply an unsafe workplace and (c) safe work practices are both needed and used to control employee exposure to chemical substances, but it is inappropriate for OSHA to use this as a basis for their finding of significant risk.

With regard to case reports of adverse health effects, there is absolutely no demonstration that the proposed requirements would have been necessary to

avoid such effects. Compliance with the general industry standards should be sufficient so that any residual risk is insignificant * * * (8-42).

In the case of this latter submission, OSHA believes that the commenter did not fully consider the guidance indicated in the benzene decision for establishing a finding of significant risk.

In accordance with the Court's ruling, OSHA feels that it has in fact presented the "best available evidence" of the risks associated with laboratory operations. As the Standard Oil comment pointed out, the studies cited in the preamble to the proposed standard on long term health effects of exposure to toxic substances in laboratories (Ex. 7-3 through Ex. 7-7) were not conclusive. However, OSHA believes that the result of the studies indicate that the increase in mortality rates among chemists is partially attributable to work in chemical laboratories.

OSHA agrees with the Standard Oil comment insofar as it states that the mere presence of an OSHA regulated substance in a laboratory should not designate it as an unsafe workplace. The point intended (at 51 FR 26665) was that laboratories commonly use OSHA regulated substances for many of which a finding of significant risk has been clearly established. The use of such substances in the laboratory, in the absence of protective measures, including those required by OSHA's current standards, increases the risk of material health impairment.

OSHA's objective in this standard is to reduce the significant risk by at least as much as do its current health standards but in a manner which is more appropriate and cost effective for laboratories. Laboratory operations involve a greater variety of potential hazards than do most workplaces. Hence, effective employee protection requires precautions and work practices not usually found in other work environments.

Since OSHA's health standards are designed primarily to control exposures to a single substance that is used constantly and usually in large quantities, they do not adequately address the risk associated with the use of multiple hazardous substances as is typically the case in the laboratory workplace. Because of the multiple chemicals used by laboratories, OSHA is unable to develop a traditional type of quantitative risk assessment. However, OSHA believes that anecdotal information such as that cited in the preamble to the proposed standard demonstrates that hazardous situations,

and thus potentially significant risks, can exist in laboratories. In many of these cases, OSHA believes that the need for employee protection such as that afforded by the final laboratory standard is clearly evident.

OSHA therefore concludes that a significant risk exists in laboratories that do not implement work practices and procedures which are at least as effective as those prescribed by this final laboratory standard.

IV. Summary of the Regulatory Impact Assessment, Regulatory Flexibility Assessment, and Environmental Impact Assessment

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. In addition, the Regulatory Flexibility Act of 1980 (Pub. L. 96-353, 93 Stat. 1164 (5 U.S.C. 601 *et seq.*)) requires the Occupational Safety and Health Administration (OSHA) to determine whether a new regulation will have a significant economic impact on a substantial number of small entities.

Consistent with these requirements, OSHA has prepared a Regulatory

Impact and Regulatory Flexibility Assessment for the standard to control occupational exposures to hazardous chemicals in laboratories. This assessment includes a profile of the universe to be covered by the standard, an estimate of the costs of compliance with both the existing health standards applicable to laboratories and this standard, assessment of the economic and technological feasibility of the new standard, and an estimate of the potential benefits expected to accrue to laboratory employees.

The Secretary has determined that this action would not be a "major rule" as defined by section 1(b) of Executive Order 12291 as it will not have an annual effect on the economy of \$100 million or more, cause major increases in costs or prices, or have any other significant adverse effects. OSHA has also determined that this action will not have a significant adverse impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Summary of Industry Profile and Costs

The rulemaking record indicates that the Laboratory Standard could potentially affect 934,000 employees in 34,214 laboratories. Laboratories that would fall within the scope of this

standard can be classified generally as industrial, clinical, and academic.

Within these major categories, subcategories have been established for the purpose of determining potential impacts. In this industrial sector, there are approximately 10,000 captive research and development (R&D) and testing labs, and 2,500 independent labs in the industrial category. Of the clinical labs, there are about 7,100 in hospitals, and 7,600 independent labs. In the academic sector, there are about 1,200 labs in private post secondary schools, 5,600 in private secondary schools, and 214 in private professional schools.

OSHA has examined the annualized costs (in 1987 dollars) of compliance for the Laboratory Standard, and for comparison, the costs that would exist if laboratories remained covered under the General Industry health standards. These costs were estimated for all affected laboratory categories and were calculated from a baseline of current compliance levels. These estimates are displayed in Tables I and II. Costs are broken out for each lab sector and by the standard's provisions, such as the development of Chemical Hygiene Plans, employee training, personal monitoring, medical surveillance, and protective clothing.

BILLING CODE 4510-26-M

TABLE I

ANNUAL COST OF COMPLIANCE WITH GENERAL INDUSTRY STANDARDS (\$)

Lab Type	Written Plans	Training	Personal Monitoring	Hood Monitoring & Maintenance	Medical Surveillance	Closed Containers	Respirators	Record-Keeping	Change Rooms		Hazard Signs	TOTAL
									Showers	Lunch Rooms		
INDUSTRIAL												
Indep. Test	30,350	75,100	287,675	633,525	360,000	1,525	42,825	42,425	720,950	26,300	2,229,675	
Captive R&D	107,900	0	2,627,500	0	770,000	0	107,100	194,500	3,304,400	226,600	7,338,000	
CLINICAL												
Hospital	86,194	0	584,117	0	0	17,324	167,276	27,619	0	80,443	962,973	
Ind. Practice	92,264	0	396,416	1,348,164	204,288	18,544	162,716	18,848	1,917,784	61,484	4,220,508	
ACADEMIC												
Post Secondary	16,992	1,122,396	386,256	1,710,504	514,800	3,216	57,816	149,316	0	24,756	3,986,052	
Secondary	75,544	446,208	184,128	1,419,096	616,000	34,160	239,792	19,824	0	18,144	3,052,896	
Professional	2,598	443,500	298,753	0	86,285	2,925	64,151	419,397	0	24,764	1,342,373	
TOTAL	411,842	2,087,204	4,764,845	5,111,289	2,551,373	77,694	841,676	871,929	5,943,134	462,491	23,123,477	
% of total	1.8%	9.0%	20.6%	22.1%	11.0%	0.3%	3.6%	3.8%	25.7%	2.0%	100.0%	

Source: Booz, Allen & Hamilton; U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE II

ANNUAL COST OF COMPLIANCE WITH LABORATORY STANDARD (\$)

Lab Type	Medical Surveillance		Chemical Hygiene Plans	Training Programs	Hood Monitoring & Maintenance	Recordkeeping	Designated Area	Personal Monitoring	TOTAL
INDUSTRIAL									
Indep. Test	270,000	53,947	303,910	9,440	633,520	23,377	199,755	1,493,949	
Captive R&D	2,250,000	43,157	0	94,400	0	151,050	1,658,625	4,197,232	
CLINICAL									
Hospital	0	61,283	0	29,491	0	71,497	405,620	567,891	
Ind. Practice	383,040	65,599	0	20,088	1,348,134	54,666	275,278	2,146,805	
ACADEMIC									
Post Secondary	364,500	20,715	750,542	10,195	1,710,507	24,761	219,478	3,100,698	
Secondary	100,800	241,681	1,281,034	2,115	1,419,096	20,140	51,150	3,116,016	
Professional	161,280	1,856	0	11,313	0	21,986	207,467	403,902	
TOTAL	3,529,620	488,238	2,335,486	177,042	5,111,257	367,477	3,017,373	15,026,493	
% of total	23.5%	3.2%	15.5%	1.2%	34.0%	2.4%	20.1%	100.0%	

Source: Booz, Allen & Hamilton; U.S. Department of Labor, OSHA, Office of Regulatory Analysis

BILLING CODE 4510-26-C

OSHA estimates that the total annualized costs would be \$23.1 million under the current General Industry Standards compared to \$15.0 million for the Laboratory Standard. Such costs would not adversely affect the competitive status of the entities in any of the laboratory categories.

Summary of Benefits

The new standard differs from many OSHA health standards in that it does not establish new exposure limits, but sets other performance provisions designed to protect laboratory workers from potential hazards in their work environment. By permitting a greater degree of flexibility to laboratories in developing and implementing employee safety and health programs, OSHA expects benefits to result from increased worker awareness of potential risks, improved work practices, appropriate use of existing personal protective equipment and greater use of engineering controls. Given the flexibility to design and implement innovative measures to reduce employee exposure to hazardous substances, employers also will reap rewards in terms of lower insurance premiums, lower property damage costs, lower turnover costs, less absenteeism and, in general, increased productivity. Finally, the potential decrease in acute and chronic health problems will result in overall benefits to society through the associated reduction in medical and productivity costs.

A substantial amount of evidence in this record indicates that laboratory workers are at risk to serious and even life threatening occupational hazards. Several companies with good work practice programs, however, indicated that these hazards can be overcome through sound safety practices, and submitted evidence of the magnitude of the benefits to be attained from this standard [Ex. 3-16, Ex. 3-24, Ex. 3-197, Ex. 42]. These companies reported accident rates 30 to 80 percent below the industry average. OSHA estimates that the benefits resulting from this standard include reductions in non-lost workday cases, lost workday cases, chronic disabling illnesses, and chemical source workplace cancers. It is projected that implementation of the standards will result in at least a 10 percent reduction in chemical-related illnesses and injuries in laboratories. Although precise estimates of current chemically related injury and illness rates in laboratories are not available, OSHA estimates that the Laboratory Standard will prevent 235 of these non-lost workday cases, 82 lost workday cases, 60 chronic disabling illnesses, and 40 cancers annually. In

addition, other benefits may be realized since improved work practices may prevent accidents or other incidents not directly attributable to a chemical source.

Technological Feasibility

OSHA has determined that the Laboratory Standard is technologically feasible. Its primary emphasis is on administrative controls necessary to protect workers from overexposure to hazardous substances in laboratories. Engineering controls such as fume hoods, vacuum systems and glove boxes, which are necessary to limit chemical exposures, are considered conventional technology in this industry. This technology is commonly known and currently can be found in nearly all laboratories.

Regulatory Flexibility Assessment

OSHA has attempted to evaluate the expected cost of compliance for small entities. However, since a majority of labs are captive of larger establishments and firms, it was not possible to determine the precise impact on all small entities. For those laboratories which are part of for-profit enterprises, the cost of the standard is estimated to be less than 0.03 percent of annual revenues.

The relatively small compliance costs associated with this standard are not expected to alter small firms investment plans, or be especially burdensome to small firms. Indeed, small firms will gain substantial cost savings as a result of the new exemption from general industry standards.

Environmental Impact Assessment

As required by the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), OSHA has reviewed the new standard and has determined that there will be no significant environmental impacts as a result of the action. The standard focuses on reducing worker risk by means of work practices and procedures and therefore is not anticipated to adversely affect ambient air quality, water quality, solid waste, or land or energy use.

V. Summary of Major Differences Between the Proposed and Final Standard

Certain provisions have been modified in the final standard to reflect comments submitted in response to the proposed standard. The following discussion summarizes the major changes.

The title of the final standard, "Occupational Exposures to Hazardous

Chemicals in Laboratories" has been changed from "Occupational Exposures to Toxic Substances" as in the proposal. The reason for this change, discussed in greater detail later in this preamble, resulted from the persuasive comments which called for consistency, to the extent possible, between the final laboratory standard and OSHA's Hazard Communication Standard (HCS). Thus, the term hazardous chemical as used in HCS, and as it relates to the definition of health hazard, has been included in this final standard.

In the preamble to the proposed standard, OSHA proposed to exempt certain laboratories (dental, veterinary and group medical practices) from coverage by the standard. The final standard does not provide for categorical exemption, but instead requires that determination of whether the laboratory standard applies be made on the basis of the definition of "laboratory scale" and "laboratory use."

Under the proposal, the laboratory standard would have superseded all substance specific health standards with the exception of the permissible exposure limits in subpart Z. There are, however, instances where the final laboratory standard will not preempt the substance specific standard in any case. For example, the use of formaldehyde in histology, pathology and anatomy laboratories will remain under the Formaldehyde Standard (29 CFR 1910.1048) as directed by that standard. All other laboratory uses of formaldehyde will be covered by this final standard.

As in the proposed standard, the final standard requires employers to develop and implement a Chemical Hygiene Plan (CHP). The CHP sets forth work practices and procedures to protect employees from health hazards in that particular workplace. The final standard responds to the recognized need for consistency in terms used in OSHA standards and further clarifies when a CHP must be implemented.

The proposed standard required employers to include in the CHP, special measures for handling carcinogens.

This final rule, however, modifies the carcinogen definition and the obligatory action so that special provisions must be explicitly considered by the employer, but need only be implemented when the employer deems them appropriate on the basis of the specific conditions existing in his/her laboratory. Moreover, the term, "carcinogen" has been replaced by "select carcinogen" which covers a narrower range of substances (see discussion below, paragraph (b) of this preamble). In addition, because it

was pointed out in the record that other substances such as reproductive toxins and acutely toxic chemicals also pose severe hazards, the final standard also requires that the same special provisions as for select carcinogens be considered by the employer in the Chemical Hygiene Plan.

The proposed standard required that carcinogens be handled in a regulated area. The final standard provides for the handling of select carcinogens where appropriate in a "designated" area, a term which is less restrictive and more appropriate for laboratory operations than the regulated area as defined in other OSHA standards.

Training and information provisions of OSHA's Hazard Communication Standard have been incorporated in the final rule so as to include physical hazards in the employer's training program as well as provide explicit training on health hazards involved.

The medical coverage afforded employees by the final standard has been revised in accord with substantial comment received. Medical attention is provided by this standard under the following circumstances: (1) Whenever an employee develops signs or symptoms associated with exposure to a hazardous chemical; (2) in the event of an occurrence such as a leak, spill or explosion resulting in the likelihood of a significant exposure; or (3) whenever an action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring or medical surveillance requirements is routinely exceeded. In this case the medical provisions of the standard must be complied with until the exposures are reduced below the action level.

In addition, when there is reason to believe that an action level is routinely exceeded, monitoring must be utilized to determine if that is the case.

VI. Summary of Issues and Explanation of Provisions of the Final Standard

The rulemaking record on which this final standard is based overwhelmingly supports the approach taken by the Agency in its proposed standard (51 FR 26660) to control occupational exposures to toxic substances in laboratories. Of the 129 written comments submitted in response to the proposal, 57 addressed the need for a separate standard for laboratories. Approximately 91% (52) of these 57 comments supported the need for the standard and agreed with OSHA's approach. (See, for example, Exs. 8-1, 8-14, 8-19, 8-23, 8-25, 8-32, 8-40, 8-64, and 8-74.) General acceptance of the concept notwithstanding, there were objections, concerns and

recommendations related to certain aspects of the proposed standard. Most of these issues were related to specific provisions and are detailed in the paragraph-by-paragraph explanation of the final standard presented below.

The comments, however, raised other issues that also warrant further discussion and explanation. One such issue is the perception that the proposed standard was duplicative in certain respects to OSHA's Hazard Communication Standard. See, for example, Exs. 8-52, 8-85, 8-88, and 8-114.

In considering the two standards, it is important to note the objectives of each. The Hazard Communication Standard is designed to ensure that employees are apprised of the hazards associated with chemicals in their workplace so that they may make informed judgments regarding the necessary precautions to protect themselves. The final laboratory standard, on the other hand, requires that employers develop a comprehensive plan to implement those practices that safety and health experts have accepted as effective in minimizing laboratory employee exposures to hazardous chemicals. These practices, if followed, obviate the need to comply with the specific provisions of OSHA's health standards except in certain instances. See the discussion of scope and application (paragraph a).

Paragraph (a). Scope and Application Preemption by Other OSHA Health Standards

As in the proposal, the final rule provides that any substance specific standard can require coverage to remain under that standard rather than under the laboratory standard. The preemption issue was raised in the rulemaking proceedings for benzene and formaldehyde as well as in comments to the proposed laboratory standard.

Dr. Emmett Barkley of the National Institutes of Health stated:

Clarification is required as to whether the laboratory standard should preempt a substance specific standard if the chemical in question is used in an ancillary process, and not directly a part of the research protocol itself (e.g. a test substance, reagent, intermediate product, etc.), even if the use of this material meets all of the criteria set forth in the definition of "laboratory use of toxic substances". (Ex. 8-58).

NIOSH further stated:

It is important to very clearly state in the final standard that compliance with this standard does not alleviate compliance with more specific standards promulgated by OSHA (e.g. ethylene oxide and its use for non-research purposes) (Ex. 8-23).

It has always been OSHA's intention that in the absence of a statement of preemption in a substance specific standard, the determination of whether the laboratory standard applies must be dependent on both "laboratory use" and "laboratory scale" criteria. Therefore, if these criteria are met, then this laboratory standard applies. The NIOSH comment specifically addressed ethylene oxide which is widely used as a sterilant. Since the ethylene oxide standard (29 CFR 1910.1047) did not expressly preclude its preemption by the laboratory standard, and even though used as a sterilant and not part of an experiment, the use of ethylene oxide in a laboratory will be covered by this standard, provided the use conforms to the "laboratory scale" and "laboratory use" definitions.

OSHA believes that adequate protection is provided by this standard in the case of ethylene oxide.

In the preamble to the benzene standard (29 CFR 1910.1028), OSHA discussed whether users of benzene in laboratories would be required to comply with the benzene standard or the laboratory standard (52 FR 34528). OSHA stated that it would give additional consideration to this issue in the context of the laboratory standard rulemaking. Three commenters to the proposed laboratory standard felt that the benzene standard should not be preempted by the laboratory standard. Air Products and Chemicals Inc. (Ex. 8-18) stated that, "When and if specific requirements regarding benzene are adopted for workplace exposure they should be added to an appropriate section of 1910 and not be buried in § 1910.1450." Exxon Company (Ex. 8-35) agreed, saying, "If exposure is such that it meets the criteria of the benzene standard, then those workers would be covered by the benzene standard." Miles Laboratories (Ex. 8-091), too, regarded coverage under the benzene standard to be most appropriate, stating, "Medical surveillance for specific chemicals of increased risk should probably be handled through the General Industry Standards." Several others disagreed (Exs. 8-19, 8-36, 8-65, 8-66, 8-107, 8-112, and 10-1), maintaining that no single substance should have special provisions. OSHA believes that under this final rule it has satisfied the real concerns of both sets of commenters.

Under the laboratory standard, routine exposure above an action level will require the same exposure monitoring and medical surveillance provisions as in the relevant substance specific standard, in this case benzene.

Therefore, by preempting the benzene standard, this laboratory standard is providing more appropriate coverage for laboratories while continuing to provide full protection consistent with employee health and safety.

When the formaldehyde standard (29 CFR 1910.1048) was promulgated in December, 1987, it stated (52 FR at 46246) that formaldehyde use in histology, pathology and human or animal anatomy laboratories will continue to be covered by the formaldehyde standard rather than the laboratory standard. The preamble further notes (52 FR at 46246) that formaldehyde exposures in other types of laboratories will be considered in the rulemaking for the laboratory standard. No comments were received in the record of the proposed laboratory standard regarding the specific coverage of formaldehyde. In the absence of any comments, OSHA sees no reason why laboratories, other than histology, pathology and anatomy laboratories, which use formaldehyde should not be covered by this laboratory standard.

OSHA believes that, with this laboratory standard in place, future rulemakings covering specific substances will have criteria by which to decide whether laboratories will more appropriately be covered by the standard being promulgated or the laboratory standard. It is not OSHA's intention to add requirements which do nothing to protect the health of workers. In order to further clarify the application of this standard, OSHA has added a new paragraph (a)(3) concerning scope and application. Paragraph (a)(3) states that this standard will not apply where the only laboratory use of a hazardous chemical provides no potential for employee exposure.

Facilities

At the time OSHA began work on this standard a major problem was that of trying to define a laboratory. There are many facilities which are referred to as "laboratories" but which clearly should remain covered by other OSHA standards and not by this one. It is important to consider the genesis of this rulemaking to clarify this issue. As the background discussion in section IV points out, the purpose of promulgating a laboratory standard was to provide a standard appropriate for situations in which small quantities of multiple chemicals would be used—each, for the most part, for a relatively brief time duration. In trying to address this situation in the proposal, OSHA developed definitions for "laboratory scale" and "laboratory use" so as to focus on the conditions of the workplace

rather than on the word "laboratory" itself. It was felt that it would be impossible to consider and categorize every establishment, or even every type of establishment, that regarded itself as a laboratory without clarifying criteria, and that a suitable course was to establish coverage in terms of the "laboratory scale" and "laboratory use" definitions to determine on the basis of a facility's specific activities and circumstances of exposure whether it was more appropriate to require compliance with the provisions of this laboratory standard or the provisions of standards covering the specific substances involved. That is to say, each facility would be judged on whether it met the criteria for the definitions of "laboratory scale" and "laboratory use." However, in preparing the proposal, it was necessary to identify categories of laboratories for purposes of analysis. Among the categories considered were veterinary and dental laboratories and those associated with group medical practices. OSHA proposed to exempt these facilities from coverage under the laboratory standard based on information then available (see 51 FR at 26672). In addition to comments received pertaining to the proposed exemptions, comment was also received regarding, in particular, whether or not facilities such as quality control laboratories and certain pilot plants should be covered by this standard.

Exemption of any laboratories was opposed by Dr. Daniel Teitelbaum of the Denver Clinic (Tr. 45), Dr. Jay Young, chemical consultant (Tr. 72-73), Dr. W. Emmett Barkley of the National Institutes of Health (Tr. 114), Mr. Frank Grimes of the United Steel Workers (Tr. 284) and Dr. Gerald Hoeltge of the American Society of Clinical Pathologists/College of American Pathologists (Ex. 43). The basic position of all these commenters was that the degree of protection afforded to an employee should not depend upon an arbitrary classification of the particular laboratory. OSHA agrees with this argument in principle, but other comments brought out that there are other relevant factors. Marcia Brody representing the American Veterinary Medical Association (Ex. 41) pointed out that veterinary "laboratories" were not really laboratories in the intended sense of this standard—that only minute quantities of substances in commercially prepared kits are used and that, in most cases, no chemical reagents were used at all. Supporting these comments were those of Dr. Cleveland Brown, a practicing veterinarian (Tr. 270) who

stated that most detailed work is sent out to the larger diagnostic laboratories. Nevertheless, Dr. Emmett Barkley (Tr. 118) testified that, in NIH veterinary laboratories, chemical solvents, anesthetic gases and medications and drugs which represent toxic hazards to employees are all used. It is apparent to OSHA that the term, "veterinary laboratory" includes a wide range of different scales of operations and that this variation must be recognized in determining where this standard applies.

Mr. Norman Steere of Norman V. Steere Associates, and Dr. Alan Todd of Stewart-Todd Associates, Inc. (Tr. 141-142) pointed out that a similar situation exists in medical laboratories, with potential exposure conditions varying significantly between various size group practices, large diagnostic laboratories and hospital laboratories. It therefore seems clear that grouping all such facilities under one designation would be inappropriate and that blanket exemptions for such designations, as proposed by OSHA, are consequently also inappropriate.

Considerable comment was also devoted to whether "pilot plant laboratories" and "quality control laboratories" should be covered by this standard or by other General Industry standards. (Exs. 8-23, 8-24, 8-25, 8-41, 8-44, 8-45, 8-46, 8-69, 8-73, 8-79, 8-92, 8-93, 8-96, 8-100, 8-107, 8-110, 10-6, Tr. 95-96, Tr. 253, Tr. 417-420, Tr. 435 and Tr. 440). Arguments were presented for both positions. However, once again, great variation exists from one to another such facility. It is important to remember that one of the reasons for this standard is to eliminate inappropriate requirements such as monitoring in workplaces which are characterized by conditions where very small quantities of frequently changing substances are used. But where the quantities are not small and where the substance in question is usually present, it is entirely appropriate to monitor and, in such cases, employee health and safety is better served by complying with the requirements of the appropriate OSHA substance specific standard.

The record amplifies the inherent difficulties in attempting to classify facilities on the basis of what label is placed on a particular "laboratory", i.e. "quality control", "group medical practice", "pilot plant," for example. Therefore, OSHA believes that judgments about specific categories cannot be made on the basis of the label placed on that category and that categorical exemptions as were made in the proposal are not appropriate.

In general, pilot plant operations are typically closely connected with production processes. Such operations would fall outside the scope of the standard because they fail to meet the "laboratory use" definition which precludes laboratory procedures that are part of a production process or in any way simulate a production process. However, the rulemaking record suggests that, in some cases, pilot plant operations are an integral part of a research function (see Tr. 453-454). For example, as pointed out by Mr. Ron Larson of Exxon Research and Engineering Company, the pilot unit may consist of several small bench operations which are combined for the purpose of evaluating a particular effect. The operations do not always proceed to production but may remain part of the research activity. In these instances, if the pilot plant operation meets all other criteria for laboratory use and laboratory scale, it would indeed be within the scope of the standard. Therefore, although most pilot plants would not likely meet the required criteria for coverage under the Laboratory Standard, there are some which do and thus a blanket exemption for pilot plants is inappropriate.

Similarly, most quality control laboratories are not expected to meet the qualification for coverage under the Laboratory Standard. Quality control laboratories are usually adjuncts of production operations which typically perform repetitive procedures for the purpose of assuring reliability of a product or a process. However, as with pilot plants, there will be exceptions, and where quality control laboratories meet the criteria of the definitions for "laboratory scale" and "laboratory use," they will be required to comply with this standard.

It is OSHA's position that the determination, in general, of what facilities are covered must be made specifically on the basis of the definitions of "laboratory scale" and "laboratory use". OSHA believes that these factors represent the appropriate criteria for describing the conditions and health hazards which make this regulatory action appropriate. Some commenters believed that these definitions should be amended so that their facilities would be covered. (Exs. 8-20, 8-46, 8-69, 8-73, and 8-118). Others felt the definitions should be amended so they would not be covered. (Exs. 8-42 and 8-44).

These comments in themselves give testimony to the fact that the criteria contained in the definitions are in most cases sufficiently clear to provide

substantial guidance as to whether a facility is considered to be covered by this standard or whether it is covered by other health standards in subpart Z.

An additional issue that was raised in the comments and hearing concerned the need to implement a Chemical Hygiene Plan when exposures are always minimal and involve substances which are of moderate or low toxicity. (See Exs. 8-79, 8-93, 10-10 and Tr. 417-418). OSHA believes that, in such cases, the standard is appropriate and reasonable because of the flexibility of the Chemical Hygiene Plan requirement. Minimal exposures to chemicals of low toxicity will require a simpler Chemical Hygiene Plan because the standard, while requiring that specific considerations be addressed, leaves it to the employer to specify how. Therefore, the employer is able to address the required considerations in a manner appropriate to the substances and conditions in the specific laboratory.

Chemicals

Reference was made in the proposed standard to the term "toxic substance" for the purpose of demonstrating when the Chemical Hygiene Plan, which outlined work practices and procedures to be taken to protect employees, was to be implemented. The term "toxic substance" was defined as any substance in 29 CFR part 1910, subpart Z as well as substances determined to be carcinogens or potential carcinogens by IARC or NTP. However, once instituted, the work practices and procedures which the CHP specified were expected to be sufficient to provide protection from all toxic or hazardous substances regardless of whether they were included in the "floor" of toxic substances specified by the toxic substance definition. As noted in the preamble to the proposed standard, (see 51 FR 26671):

*** [T]he impact of the standard is potentially broad since most laboratories would handle at least one substance which falls under one of the two categories and would therefore be required to implement work practices which would serve as effective protection against substances not explicitly covered by the standard but which may be potentially hazardous.

In the final standard, the term "hazardous chemical" is used in lieu of "toxic substance." The reason for this action is explained in greater detail later in this discussion.

Early in the rulemaking activities for this standard, OSHA's information indicated some important factors to be considered in developing a standard for laboratories: (1) The implementation of carefully designed work practices and

appropriate training are key to effective workers protection; (2) the diversity of laboratory operations would best be addressed by using a performance approach in which appropriate work practices and procedures are determined by the employer; and (3) compliance with good laboratory practices, accepted by safety and health experts as effective, would obviate the need to comply with specific requirements prescribed in OSHA's substance specific health standards for maintaining PELs.

Accordingly, on the basis of this information, OSHA proposed that employers develop a Chemical Hygiene Plan as a mechanism to provide employee protection regarding substances regulated by OSHA as well as other potentially hazardous chemicals used in the laboratory. However, considering the number of comments which expressed an opinion regarding which substances the standard should address, it became obvious that the intended purpose of the Chemical Hygiene Plan, outlined in the proposal, was not clearly conveyed.

Many commenters urged OSHA to expand the definition to include more substances, increasing employee protection from exposure to a greater number of harmful substances used in laboratories. Various suggestions were made on how OSHA should expand the scope of substances to be covered. Commenters (Exs. 8-15, 8-20, 8-22, 8-25 and 8-97) specifically recommended that the toxic substance definition at least include the ACGIH ILV list. For example, Kent R. Weber of J. T. Baker Chemical Company stated:

The proposed rule uses OSHA PEL requirements to trigger the activation of this standard. Because the PEL's can only be updated by a lengthy rulemaking process, *** ACGIH TLV's are a better and more up-to-date list of standards. Use of ACGIH limits provides workers with the benefit of more current information and is more sensitive to the dynamic process of science as hazard investigations are carried out. As the preamble to the proposed rule indicates, only violations of the OSHA PEL standards would result in a citation, so use of ACGIH TLV's should not pose a regulatory burden on labs. (Ex. 8-97).

A similar view regarding the limitation of the proposed toxic substance definition was presented in the testimony of Dr. Alan Todd, Director, Industrial Hygiene for Stewart-Todd Associates, Inc. and expert OSHA witness:

We concur with adding *** the professional, updated guidelines incorporated in the ACGIH TLV's *** I suggest that

others, such as the AIHA, meaning the American Industrial Hygiene Association, Workplace Environmental Exposure Levels along with some of the NIOSH criteria, where there is no OSHA PEL, be incorporated by reference to supplement the PELs *** (Tr. 91).

Other participants in the rulemaking proceedings suggested that the scope of substances covered by the laboratory standard should be consistent with that of the Hazard Communication Standard (§ 1910.1200). Testifying as an expert OSHA witness, Dr. Jay A. Young, a chemical consultant, offered the following recommendation:

*** The substitution of the term "hazardous chemical" as defined in the hazard communication standard for the term "toxic substance" as defined by the proposal will substantially increase the effectiveness of the proposed rule in preventing exposures to substances that are toxic but not now included in subpart 7 nor in the IARC or NIP carcinogen lists. There are only a few hundred chemicals that are toxic included in subpart Z and the carcinogen lists; there are thousands of other chemicals that are toxic and that are also used in laboratories and which should be included in the purview of the proposed rule. A few of these taken at random from a current laboratory supplier catalogue will illustrate my point. All of the following are toxic. None are included within the presently proposed rule *** Hazardous chemicals such as vanadates; selected bismuth compounds; acetyl halides and derivatives; hydroxylamine hydrochloride; selected indium compounds, perchloric acid and selected derivatives; phosphorous oxychloride; phosphorous (III) and (V) halides; sulfuric acid; sulfuric acid (in addition to the fluoride); selected tetramethyl ammonium derivatives ***

To reduce the risk of harm in chemical laboratory work, chemicals such as the above should be included, just as they already are included under the hazard communication regulation (Tr. 70-71).

Consistency between HCS and the final laboratory standard in terms of substances covered was also recommended by Dr. Frank R. Ciofalo on behalf of Cal/OSHA:

The term "toxic substances for laboratories" will get confused with "hazardous substances" for HCS as well as the specific definition of "toxic" and "highly toxic" in HCS. Therefore, the exact terminology should be transported to the CHP." (Ex. 8-28).

Similarly, David Chawes, Senior Industrial Hygienist for the Ecova Corporation commented:

The definition of toxic substances proposed is at variance with the existing OSHA definition of toxic substances used in the Chemical Hazard Communication Standard. This variance is unacceptable, because many institutions and employers with laboratories have already adopted the

Hazard Communication definition *** To introduce a new definition of "toxic" *** would be counter-productive and would result in employee and employer confusion. (Ex. 8-34).

Although the majority of participants supported the need to expand the scope of substances covered, there were, however, some commenters who opposed coverage beyond OSHA regulated substances. For example, the written submissions of Exxon Company U.S.A. (Ex. 8-35) and Monsanto (Ex. 8-36) shared the concern expressed by Hoffman-LaRoche who stated:

*** [W]e believe that coverage by this standard should be limited to substances for which there is an OSHA PEL. There are several difficulties in including the ACGIH TLV standards; it would give them a pseudo-regulatory status; *** we strongly urge that before ACGIH TLVs are even suggested as "guidelines," they be published as proposed additions to OSHA's list of PELs with an opportunity for comment (Hoffmann-La Roche Inc., Ex. 8-111).

In response to these latter comments, OSHA would like to reiterate the argument it made in the preamble to the proposed standard regarding the appropriateness of including under the scope of the standard substances determined to be carcinogenic by IARC or NTP. As stated at (51 FR 26665):

OSHA determined in the Hazard Communication Standard that it was appropriate to require certain procedural provisions for substances for which OSHA had not set an exposure limit and that this type of provision was much lesser in scope than setting an exposure limit and that the appropriate legal analysis was the discussion by the Supreme Court of "backstop" provisions in *Industrial Union Dept. v. American Petroleum Institute*. (See the discussion at 48 FR 53296-9, 53321 and at 448 U.S. 697, 658.) ***

OSHA believes that this reasoning is equally appropriate (inclusion of substances for which there is no PEL) for the purposes and intent of this standard.

This standard was designed expressly for laboratories to address the unique exposure conditions under which work is performed and to protect employees from adverse health effects that may result from their work in laboratories regardless of what toxic and hazardous substances are used. In contrast to those who argued that OSHA's authority with respect to the protection of laboratory workers should be restricted to OSHA regulated substances, OSHA believes that any standard of this nature which does not include consideration of all potentially hazardous chemicals would not be an appropriate solution to providing the desired level of employee protection. This standard sets no

exposure limits or threshold limit values. However, because substances which are involved in laboratory use are acknowledged to produce adverse health effects which could result in significant risk, then certainly protective measures are appropriate.

Supporting the concept of an all inclusive standard, the Chemical Manufacturers Association (CMA) suggested that a standard which applied only to PEL substances would be less protective than one which applied to a broad range of hazardous substances whether regulated or not. As George Stout, representing CMA, concluded in his testimony:

The current PELs have little impact on the total exposure hazard of most laboratories. The overwhelming number of materials handled in laboratories have no PELs. Often the toxicity information is scanty or non-existent. A performance-oriented good laboratory practices approach helps reduce risk for both regulated and unregulated materials. (Tr. 251).

OSHA agrees with the arguments submitted to the record which suggested that where feasible there should be consistency in its standards so as to eliminate confusion with respect to compliance and ensure the greatest measure of employee protection. Such is the case with the final laboratory standard. Laboratories in the manufacturing sector, as well as other laboratories as a result of the expansion of scope of the Hazard Communication Standard (52 FR 31852, August 24, 1987), are covered by certain provisions of that standard. The term hazardous chemical, is used in the Hazard Communication Standard. To introduce a new term, "toxic substances," which lists fewer chemicals regarded as hazardous to laboratory workers could create confusion. (See, for example, Exs. 8-28 and 8-34).

In view of the comments submitted and the recognized need for consistency, OSHA has decided to incorporate the term hazardous chemical into this final standard. However, the use of this definition makes no change in the intent evinced in the preamble to the proposed standard. It should be recognized that, while appearing to enlarge the impact of the standard, this action will actually create little additional burden to employers. The intent has always been to mandate the implementation of an overall Chemical Hygiene Plan for the entire laboratory whenever any substance included in the scope of the standard was present. Therefore, any substance regulated by OSHA would automatically trigger the program for the laboratory as a whole. Since very few

laboratories will be free of all regulated substances, most laboratories would need to comply with this standard even if the scope were limited to such substances. The expansion of the scope to cover all "hazardous chemicals" should add few workplaces to those which will need to comply anyway. The addition of the term hazardous chemical will further clarify the fact that the laboratory employer must offer protection to all employees in all laboratory work situations.

Inclusion of Safety Hazards

In a related matter, OSHA requested comments and information on the appropriateness of developing a vertical standard for laboratories, covering both safety and health hazards. Some commenters (Exs. 8-20, 8-38, 8-70, 8-74, 8-75, 8-76, 8-108, 10-12 Tr. 47, Tr. 129, Tr. 285, and Tr. 294) recommended that OSHA include measures to protect laboratory workers from additional hazards such as biological, radiological and physical hazards such as fire and explosion. For example, the AFL-CIO stated:

* * * Chemicals which pose health hazards may also pose fire and explosion hazards. Health hazards are not limited to toxic chemicals, but include biological agents and physical agents like radiation. Any standard designed to protect laboratory workers should not make artificial distinctions between toxic chemicals and other agents and between health hazards and safety hazards. Control measures should consider the laboratory environment as a whole and respond to all hazards present. The standard should be expanded to [provide] comprehensive coverage of toxic chemicals, biological and physical agents and both health and safety hazards. (Ex. 8-75).

Mr. Chain Robbins, manager of Health and Safety for International Technology Laboratories, emphasized the need to address physical hazards in this standard. Mr. Robbins stated:

* * * It has been the experience in International Technology Laboratories that physical hazards have been those which have caused the most significant worker injuries * * * We believe that any laboratory standard for worker protection must include requirements for employers to address the physical hazards identification and controls necessary to prevent losses. (Ex. 8-74).

Norman Steere, consultant on laboratory safety, also urged OSHA to include biological and physical hazards under the standard. Mr. Steere stated:

* * * I believe that the proposed standard should apply to all of the hazards encountered in laboratory workplaces, including physical and biological hazards * * * Although I am personally unaware of any deaths that have resulted from laboratory exposure to toxic chemicals, I do

know of several deaths that have occurred from laboratory-acquired infections, and from laboratory fires or explosions, so I conclude that to omit the physical and biological hazards may be omitting a major portion of the problem (Tr. 129).

Dr. Alan Ducatman of MIT advised OSHA to complete the initiative that it had already begun and revise the standard to incorporate protective measures for other laboratory hazards at a later date. In response to a question regarding his position on whether OSHA should include biohazards under the proposed laboratory standard, Dr. Ducatman replied:

I think it's so important that this proposal go through, that I would certainly be willing to see it go through without that. But, I would like to see, eventually, biohazards wrapped in. If not immediately, eventually, and that is because as our institutions become more technical, biology and chemistry are merging. In fact, biology, chemistry, and physics are merging. I think it is important that we try we get the most universal standard that we can.

At this time, I don't think you have to do that. I think you should make it a future goal. (Tr. 183)

OSHA recognizes that laboratory employees may be exposed to potential hazards that are not addressed by this standard. However, since the initial emphasis for a separate laboratory standard was directed toward the inappropriateness of OSHA's health standards for laboratory work, the record is not completely developed regarding other hazards facing laboratory personnel. While this standard exempts laboratories from most provisions of subpart Z, other subparts of 29 CFR 1910 which address physical hazards remain in effect for laboratories. For example, laboratories and other general industry employers must comply with subpart H which pertains to hazardous materials and includes regulations for compressed gases and flammable and combustible liquids and subpart G—Occupational Health and Environmental Control—which contains regulations for noise exposure and radiation.

Moreover, other comments indicated that OSHA's safety standards which cover physical hazards do not present the same type of compliance problems for laboratories as do its health standards. Such views expressed by Exs. 8-9, 8-18, 8-19, 8-36, 8-42 and 8-66 were similar to the following comment submitted by Eastman Kodak Company:

We believe the rule, as proposed, should be limited to regulations of occupational exposures to toxic substances in laboratories and should not extend to cover other general laboratory safety issues which are currently addressed in other OSHA standards, such as flammability, corrosivity, and explosivity.

Such hazards in laboratories are not significantly different from those in general industry, and attempts to incorporate protection against such hazards in this proposed rule would delay and complicate the development of appropriate Chemical Hygiene Plans. (8-118).

OSHA believes that the requirement for training on physical hazards, in conjunction with current safety regulations, should improve effective employee protection. Therefore, although the final laboratory standard does not dictate provisions for work practices to protect employees from potential physical hazards associated with chemicals used in their work areas, it does require that such physical hazards be addressed in the employer's training program. (See 29 CFR 1910.1450(f)(4)(B).)

Currently, OSHA has no regulations which specifically address biological hazards. However, the Agency has issued a proposed rule entitled "Occupational Exposure to Bloodborne Pathogens" (54 FR 23042, May 30, 1989). When the Agency promulgates a final standard on this subject, laboratory workers would be included under its coverage. Meanwhile, several guidelines are available which make recommendations pertaining to biosafety for laboratories. For example, the Centers for Disease Control and the National Institutes of Health have jointly published "Biosafety in Microbiological Laboratories." In addition, the National Committee for Clinical Laboratory Standards has recently issued a proposed guideline entitled "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood and Tissue."

Because of the aforementioned considerations, including the record evidence, OSHA believes that the focus of this final standard is appropriate and addresses the most critical areas of need with respect to laboratory worker protection.

Paragraph (b) Definitions

The proposed standard contained definitions to facilitate interpretation of its provisions and intent. Extensive explanation was provided in the preamble for those definitions which were unique to the proposed standard. In the final standard, certain definitions remain unchanged from the way they were proposed since there was little or no objection in the record regarding their content or purpose.

The following terms are defined identically in the proposed and final standard: "Assistant Secretary", "Chemical Hygiene Officer",

"emergency", "laboratory-type hood", and "protective laboratory practices and equipment." The explanation for certain of these terms is repeated in this discussion of definitions to assure that their original intent is clearly conveyed in the final standard.

The final standard retains the proposed definition for "Chemical Hygiene Officer." As defined, the "Chemical Hygiene Officer" is an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the employer's Chemical Hygiene Plan. Use of this term is not intended to place any limitations on the job title or position description which the designated individual shall hold within the employer's organization. Consequently, the term "Chemical Hygiene Officer" may apply to another job title provided that the designated employee is technically competent to fulfill the responsibilities of developing and administering the employer's Chemical Hygiene Plan.

As in the proposed standard, the term "laboratory" is broadly defined by intention in the final standard. The basis for this standard focuses on the conditions of chemical usage commonly found in laboratories and not on the particular classification or category of laboratory operations. Although certain categories of laboratories have been mentioned for purposes of preparing cost estimates, the determination of which laboratories are covered by this standard will be based on whether or not conditions of "laboratory use" and "laboratory scale" as defined in the standard exist in the particular workplace.

As a result of changes to the proposed standard, certain proposed definitions were deleted in the final standard because they were no longer relevant. "Closed system" and "exposure evaluation", for example, are neither referenced in the final standard nor included in the final standard's definitions.

In some cases definitions have been substituted for the proposed terms and in other cases definitions have been added or amended for clarification. For example, the term "hazardous chemical" substitutes for "toxic substance" defined in the proposed standard. The term "hazardous chemical" used in this final rule relies on the definition of "health hazard" found in the OSHA Hazard Communication Standard. As discussed in the scope and application section above, commenters urged OSHA to maintain consistency in terms between the Hazard Communication Standard

and this final standard since laboratories are subject to both regulations. Therefore, in the final standard the Agency incorporates the term hazardous chemical which is defined as any substance which meets the definition of health hazard under the Hazard Communication Standard.

In a similar action, OSHA has substituted the term, "designated area" in the final standard for "regulated area" defined in the proposed standard. "Regulated area" is a term that is used in most of OSHA's substance specific health standards. Typically, it refers to an actual demarcation that is established in the work area to minimize and restrict the number of employees exposed. Also, under the 13 carcinogen standards, specific procedures such as showers and attendance lists were required for those working in regulated areas. Commenters objected to the proposal's requirement that work with carcinogens be performed in regulated areas, perhaps because of the way the term had been used in other standards (see e.g., 29 CFR 1910.1008 (c), (d)(3), (f), (g)).

The primary purpose of the "designated area" is to focus attention on the fact that a particularly hazardous substance is being used and to ensure, where appropriate, that appropriate protective measures are observed by employees working in or near the vicinity. The purpose is not to restrict the use of large areas of laboratory space. Since the term "regulated area" has a more restrictive meaning in other OSHA standards, OSHA decided it was unnecessarily confusing to use the same term in this standard to mean something less restrictive. Therefore, OSHA has decided to use the term "designated area" in the final standard in lieu of "regulated area". "Designated area" means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

The proposed standard did not define employee. Recommendations that the term be defined were included in the record, see for example, Exs. 8-32, 8-96 and 8-104. The final standard defines employee as an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments. Such individuals may actually work in the laboratory or because of their work assignments may be required to enter a laboratory where potential exposures may occur. In the latter category, OSHA considers maintenance and custodial

personnel as meeting the definition of employee. The definition of employee would not include occasional visitors to the laboratory such as guests or sales personnel.

The term, "carcinogen," as defined by the proposed standard has been replaced by the term "select carcinogen" in the final standard. The proposal defined a carcinogen as a substance regulated by OSHA as such or identified by IARC or NTP as a carcinogen or potential carcinogen. Under the proposal, laboratories working with carcinogens were required to implement more rigorous procedures under their CHP, including the use of fume hoods. Objections were raised to this blanket approach (see e.g., Exs 8-19, 8-107, 10-9 and Tr. 112-113). Many substances in this category could be regarded as weak carcinogens, particularly in the context of laboratory use. Therefore the final laboratory standard uses a modified term, "select carcinogens," in defining those chemicals for which additional carcinogen provisions, including the designated area provision, may apply.

As noted above, the final standard defines "select carcinogen" as any substance regulated as a carcinogen by OSHA, and known human carcinogens identified by IARC or NTP. Potential carcinogens listed by IARC and NTP are considered "select carcinogens" for purposes of this standard only if they meet the stated criteria for demonstrating moderate to high carcinogenic potency in animal studies.

The definition of "Chemical Hygiene Plan" has been amended in a minor way to clarify that its purpose is twofold. It is a written plan which is to be developed and implemented by the employer that sets forth procedures, and other work practices which are capable of: (1) Protecting employees from the health hazards associated with hazardous chemicals in that workplace and (2) meets the requirements outlined in paragraph (e) of this section. Paragraph (e) specifies the elements to be addressed and instructs the employer to ensure that the CHP is capable of keeping employee exposure below designated PELs.

The definition of "laboratory scale" is retained in the final standard. The purpose of this definition is to focus on the magnitude of the operations which are covered. OSHA rejected the option to specify quantity limits as criteria for "laboratory scale," realizing that any limit specified would be arbitrary. However, the concept of quantity is certainly relevant. Therefore, the most reasonable approach is to define laboratory scale in relation to the size of

containers used in reactions, transfers and other operations and, in general terms, to the quantity of materials handled. The proposed definition of "laboratory scale" referred to work with substances in which the containers used for reactions, transfers and other handling of substances are designed for manual use, being small enough to be easily and safely manipulated by one person. The final standard revises the definition slightly to eliminate the requirement that containers be manipulated manually. Several commenters (see Exs. 8-112 and 10-2) pointed out that laboratory work frequently involves automated procedures. It was not OSHA's intention to exclude such operations from coverage. Other comments (Exs. 4-45, 8-50, and 8-64) suggested that the definition be amended to allow for non-routine tasks such as assistance from co-workers in handling 5-gallon drums and gas cylinders used in laboratory operations. As pointed out in the preamble to the proposed standard at 51 FR at 26673, the intent of the definition is not to exclude the use of facilitative mechanical aids when needed (and similarly would not preclude the assistance of co-workers when necessary). OSHA believes that the definition of "laboratory scale," as revised, is broad enough to satisfy the concerns of these particular commenters without further revision.

The definition of "laboratory use of hazardous chemicals" modifies the proposed term "laboratory use of toxic substances" in a minor way. A new criterion has been added to read as follows: "The procedures involved are not part of a production process, nor in any way simulate a production process."

For the sake of clarification, OSHA wishes to point out that criterion (d), "protective laboratory practices and equipment are available to minimize the potential for employee exposure to hazardous chemicals," is not intended to imply that such practices are implemented and such equipment are available in a particular laboratory. Rather the intent refers to the fact that a body of information, accepted by safety and health experts, is available regarding the effectiveness of such practices and equipment in protecting laboratory workers. It was never OSHA's intention to exclude laboratories from coverage by the standard in the event these practices and equipment were not immediately available in a particular laboratory workplace. To the contrary, OSHA believes that any laboratory in which this criterion is not met currently clearly

stands to benefit significantly from this standard.

OSHA has concluded, on the basis of persuasive arguments in the record, (see, for example, Exs. 8-9, 8-20, 8-74) that the final laboratory standard should include training on "physical hazards" consistent with the Hazard Communication Standard. Therefore, the definition of physical hazard as used in the Hazard Communication Standard as well as the definitions of associated terms are incorporated in the final laboratory standard.

The final standard also includes a definition for "reproductive toxins," since employers will be required to include additional protective measures in the Chemical Hygiene Plan where appropriate for work involving such substances. The final standard defines "reproductive toxins" the same way as the Hazard Communication Standard.

Paragraph (c). Permissible Exposure Limits

The final standard retains the requirement that laboratories comply with the permissible exposure limit (PELs) in effect for general industry. The Agency determined that such action was necessary to ensure that there would be no diminution in the health protection of laboratory workers.

OSHA has reviewed the complete record established for this rulemaking and has found no opposition to retaining compliance with the existing PELs. However, the comment submitted by Public Citizen (Ex. 8-70) made OSHA aware of a need to clarify what constitutes a permissible exposure limit for purposes of this standard. Public Citizen pointed out that OSHA proposed to retain permissible exposure limits (described as measurement of an 8-hour time weighted average) but did not mention the short-term exposure limit (STEL) in effect for some OSHA regulated substances. The comment correctly indicated that short-term exposures may be more dangerous than an equivalent dose occurring over a longer period of time.

Reference to permissible exposure limits does not cover 8-hour time-weighted averages (TWAs) only. The air contaminants standard (29 CFR 1910.1000), for example, designates ceiling values, acceptable ceiling concentrations as well as 8-hour time-weighted averages for various substances. Certain substance specific standards include both 8-hour TWAs and STELs under the term permissible exposure limit. (For example, see Occupational Exposure to Formaldehyde (52 FR 46292, December 4, 1987), and Occupational Exposure to

Benzene (52 FR 34563, September 11, 1987).)

For purposes of this standard, permissible exposure limit refers to any established OSHA exposure limit whether it be a TWA, ceiling, STEL, or excursion. In addition, prohibition of eye and dermal contact where specified by an OSHA standard also remains in effect.

Paragraph (d). Employee Exposure Determination

While most agreed with the concept of requiring laboratory compliance with existing PELs, two commenters pointed out that the lack of monitoring and medical examination requirements left open the possibility that an employee could be exposed to levels greater than permitted by an OSHA limit for a substance and have less protection than an employee in a workplace covered by the relevant substance specific standard. Margaret Seminario of the AFL-CIO stated that:

The standard should require that initial environmental monitoring be conducted for chemicals and agents which are used on a regular basis (i.e. more than 30 days a year). If exposures are more than one half the permissible exposure limit, semi-annual monitoring should be conducted until 2 consecutive sets of measurements show exposures below the action level. This is similar to the monitoring requirements under other OSHA health standards. Laboratory workers who are exposed to chemicals and agents on a regular basis should be afforded the same degree of protection. (Ex. 8-75).

Dr. Daniel Teitelbaum of the Denver Clinic Medical Center also pointed out the need for consideration of action levels in addition to exposure limits:

In this standard, air monitoring is not required because of the highly variable nature of exposures which might occur in the laboratory. For many substances, usage will be brief and transient and these materials must be used in hoods or with other gear which should protect the users. For some substances like lead and arsenic, however, exposures even below the PEL may cause physiological changes which indicate early toxicity.

For those materials for which a specific definition of exposure at some level below the PEL such as the action level for lead, has been included in another standard, that definition of exposure should be the applicable definition when these chemicals are used in the analytical work of the laboratory. Such provisions should apply particularly to lead, arsenic, asbestos, acrylonitrile, and many other materials for which there is good data on adverse, but sub-clinical, effects of low exposure. (Tr. 38-39).

In reviewing the issues raised in these comments, OSHA considered several points. First, in establishing a standard

particularly appropriate to laboratories, it was never OSHA's intention to allow a lesser degree of protection for laboratory employees than for other employees.

Second, this standard is based on the premise that laboratories should be accorded special treatment partly because quantities of particular substances are small and the substances themselves are frequently changing. If these conditions did not occur there would be no need for a separate laboratory standard and the workplace should remain subject to the other OSHA General Industry standards as required. Therefore, OSHA concurs with the comments from Ms. Seminario and Dr. Teitelbaum. Since minimal exposures are a premise of this standard, OSHA considers it appropriate that, where exposures are routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring or medical surveillance requirements, the employer shall comply with those exposure monitoring and medical surveillance requirements. By use of the word "routinely," OSHA intends to convey a condition which would be similar to an industrial setting where the ambient concentration of a substance is at a characteristic level as a result of the workplace conditions and the particular process involved. Factors which might raise the possibility of overexposure include the following: (1) The manner in which the chemical procedures or operations involving the particular substance are conducted (e.g. use of open vessel instead of a closed system); (2) the existence of historical monitoring data which shows elevated exposures to the particular substance for similar operations; (3) the use of a procedure which involves significant quantities or is performed over an extended period of time; or (4) signs or symptoms of exposure (e.g. skin and eye irritation, shortness of breath, nausea, headache, etc.) which are experienced by the employee.

The final standard requires that if, based on conditions such as those cited above, there is reason to believe that a regulated exposure level related to a standard which contains exposure monitoring and medical surveillance requirements is present in excess of the action level (or in the absence of an action level, the PEL), then the employer must conduct employee exposure monitoring for the substance in question. If it is found that the action level or PEL is routinely exceeded, then the employer must comply with the monitoring and

medical provisions of the relevant standard until the exposure level is brought to or below that prescribed by the particular standard or until the substance is no longer used in the same procedure. If the exposure monitoring discloses a level below the action level (or PEL where no action level exists), then no further monitoring is required and the employer continues to comply only with this laboratory standard. However, it should be noted that termination of monitoring as prescribed by the relevant standard for a particular overexposure episode does not preclude future monitoring in accordance with the requirements in paragraph (d)(1) for recurring exposure to that particular substance.

Since, as stated earlier in the discussion of this paragraph, this standard is justified on the basis of limited exposures, this provision will impose no burden at all on most employers, and where exposures are high, it will place no unreasonable burden on employers.

Paragraph (e) Chemical Hygiene Plan

The final standard retains the provisions for a written Chemical Hygiene Plan (CHP) that is to be formulated and implemented by the employer. The CHP must outline specific work practices and procedures which are necessary to ensure that employers are protected from health hazards associated with hazardous chemicals with which they work.

The Chemical Hygiene Plan concept was generally supported in submissions to the record (see e.g. Exs. 8-10, 8-20, 8-27, 8-73, 8-97, 8-106 and 10-16). The importance of such plans in providing employee protection was indicated by the Procter and Gamble Company:

Written safe work practices are often the most important component of a good safety program, especially when they are used as the basis for periodic education and training of employees. The written Chemical Hygiene Plans (CHP) required in the proposal are appropriate for laboratory uses of toxic substances. Consistent with the performance orientation, the final standard should list the elements to be addressed in the CHP, while allowing maximum flexibility for employers to develop the appropriate CHP's for their laboratory operations. (Ex. 8-73).

A question asked during the course of this rulemaking was whether a CHP would be required for each individual laboratory in establishments with many separate laboratory operations or whether a single, facility-specific plan would suffice. Considering the performance orientation of this standard and the diversity in laboratory operations, OSHA believes that this

question should be decided locally by the facilities covered. Ideally, the plan should be specific enough to a particular workplace that it does not require employees to familiarize themselves with extraneous material that is not relevant. However, it is not the intention of this standard to dictate the approach that the employer may find effective in meeting the objectives of the CHP or the manner in which it is implemented.

The final standard, like the proposal, specifies certain elements that must be addressed by the CHP but generally leaves the particular details to the employer's discretion. Non-mandatory guidance on the development of an acceptable and effective Chemical Hygiene Plan is provided in Appendix A.

The term "hazardous chemical" (replacing toxic substance as defined in the proposed standard) is defined for the purpose of demonstrating when the CHP is to be implemented. Thus, if any chemical meeting the definition of "hazardous chemical" as it relates to health hazards is used by the laboratory, the CHP is to be implemented for the laboratory in general and must automatically cover any hazardous chemical present.

The employer's Chemical Hygiene Plan must be readily available to employees, employee representatives and, upon request, to the Assistant Secretary or designee. The employer must review the CHP at least annually and update it as necessary.

The Plan must include several specific elements which are deemed necessary to ensure laboratory employee protection. Although specific elements are required, they are general enough to allow a performance approach. Furthermore, in view of the fact that most laboratory employers already have health and safety programs which include some or most of these elements the specification does not impose a significant regulatory burden on employers.

The employer's Chemical Hygiene Plan must incorporate standard operating procedures (SOP's) which are appropriate for the particular laboratory workplace for all work involving hazardous substances. Only a few comments in the public record addressed standard operating procedures. Three commenters (Exs. 8-20, 8-106 and 10-16) supported the provision as essential in performing work with toxic and hazardous substances. Other commenters (see Exs. 8-84, 8-95 and 8-114) suggested that the provision was too restrictive, particularly for research settings.

However, further examination of these particular comments underscored what OSHA believes was a lack of understanding of the intended purpose of the provision.

OSHA did not specify the contents to be covered under the SOP's, as they would vary with each facility and would best be determined by the employer. The purpose of SOP's is to assure that work practices and policies that the employer may deem necessary to protect employees from chemical hazards in the laboratory are in place. SOP's, for example, may specify general safety precautions (e.g. safety glasses, eating and drinking area restrictions, general housekeeping practices) accident response, disposal procedures and spill clean-up procedures.

The employer must also include in the plan criteria which would invoke the use of specific exposure control measures. Such criteria may be based on the degree of toxicity of the substances to be used, the exposure potential of the chemical procedures to be performed and the capacity of the engineering controls, administrative practices or protective equipment to control employee exposures effectively. Additional requirements must be included in the CHP where appropriate to protect employees working with particularly hazardous chemicals such as select carcinogens, reproductive toxins and chemicals exhibiting a high degree of acute toxicity.

The final standard also requires that employers incorporate in their Chemical Hygiene Plan measures to assure the proper functioning of fume hoods and other protective equipment. As in the proposed standard, the final standard does not specify face velocities for fume hoods. OSHA's rationale for this approach was explained in the preamble to the proposed standard (see 51 FR at 26671). In brief, the preamble stated that OSHA recognized that there was considerable debate over what optimum velocities should be in light of differences in hood design and methods of operation. Moreover, it was felt that requiring specific face velocities was not consistent with the performance orientation of the standard.

Most commenters agreed with OSHA's approach in not specifying face velocities for fume hoods. For example, the Aluminum Company of America stated:

OSHA asked whether the Standard should specify face velocities for lab hoods. We feel it should not include a specification because ventilation needs vary with the specific design and use of lab hood. Nevertheless, adequate and continuing performance of lab hoods is critical to employee health

protection and we support the requirement that the Chemical Hygiene Plan address the proper use and functioning of laboratory hoods. (Ex. 8-46).

Other commenters sharing this view included Exs. 8-18, 8-19, 8-20, 8-36, 8-42, 8-48, 8-58, 8-65, 8-79, 8-91, 8-107, 8-111 and Tr. 137-139. There are some comments in the record which suggest a need for OSHA to specify face velocities for fume hoods in the final rule. (See e.g. Exs. 8-66, 8-96, 8-108 and 10-14). However, these comments offered little or no substantive information to persuade OSHA to abandon the performance approach which allows the employer to determine the appropriate face velocities on the basis of design, use patterns and other factors which influence the effectiveness and proper functioning of the fume hood.

In addition, the employer's Chemical Hygiene Plan must identify those procedures, activities or operations which the employer believes to be of a sufficiently hazardous nature to warrant prior approval from the employer or the employer's designee before implementation.

The CHP required by the final standard retains many of the elements of the proposed standard. Certain revisions have been made, however, in response to comments and evidence in the record. In particular, OSHA has altered its position regarding the handling of carcinogens under this final standard. Under the proposed standard employers were required to include in the CHP additional protective measures for work with carcinogens. A carcinogen was defined as a substance that met one of the following criteria: (1) Is regulated by OSHA as a carcinogen or (2) is identified by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) as a carcinogen or potential carcinogen. (See 51 FR at 26678).

The additional protective measures that were to be taken when handling these substances included: (1) Establishing a regulated area, defined as a laboratory, an area of a laboratory or a device such as a laboratory hood for which access is limited to persons who are aware of the hazards of the substances in use and the precautions that are necessary; (2) requiring that all work be conducted in a fume hood or equivalent containment device; (3) specifying procedures for the protection of vacuum lines and pumps from contamination and the safe removal of contaminated wastes; and (4) specifying personal hygiene practices and appropriate protective apparel for work in a regulated area.

Numerous comments were submitted on the approach taken in the proposed standard with respect to carcinogens and the relationship of carcinogens to other highly toxic substances which give rise to both chronic and acute effects. Regarding the proposed standard's overall approach to carcinogens, specific issues were raised that included: (1) The carcinogen definition; (2) the application of identical requirements for all substances identified as carcinogens without regard to potency, concentration, physical properties or use conditions; and (3) the rationale for requiring special provisions for work with carcinogens while allowing employers to determine appropriate employee protection for work with other substances considered to be equally hazardous.

The proposed carcinogen provisions proved to be controversial. In several cases (see Exs. 8-12, 8-59, 8-95, 8-96, 8-118, and 10-9) commenters recommended that the definition be restricted to OSHA regulated carcinogens, suggesting that otherwise more stringent precautions would be imposed on laboratories than on other industries using the same materials. These comments also objected to the inclusion of substances listed by IARC and NTP since such substances had not been subjected to the regulatory review process. With respect to these particular concerns, it is important to remember the premise upon which the proposed standard was based, i.e., the need for special considerations for the laboratory use of toxic and hazardous substances regardless of their regulatory status.

A significant number of commenters (see Exs. 8-19, 8-20, 8-26, 8-30, 8-37, 8-41, 8-52, 8-66, 8-68, 8-69, 8-84, 8-93 and 10-5) expressed concerns that the carcinogen definition and associated provisions did not consider the wide variation in carcinogenic potency nor make allowances for such factors as concentration, quantity, physical properties or conditions surrounding the substances' use. The following excerpts are examples of comments addressing these particular concerns:

The California Institute of Technology, (Ex. 8-30) stated:

In the description of the chemical hygiene plan * * * the rules call for "additional employee protection for work with carcinogens or potential carcinogens as defined herein" * * * The problem is that weak and negligible carcinogens (using the OSHA definition of a carcinogen) would be included * * * Including weak or negligible carcinogens in the list of chemicals that require additional employee protection would actually do a disservice to employees because it would dilute the attention paid to

the hazards involved in the use of truly toxic materials.

Conoco (Ex. 8-69) stated:

Conoco appreciates the difficulty of defining "toxic substance" in order to prescribe appropriate work practices for carcinogens and potential carcinogens. However, the standard as written does not permit the employer to take into account the potential health hazards related to relative potency and degree of exposure. Conoco is concerned that without such flexibility the standard will needlessly burden employers by requiring restrictive work practices, such as regulated areas, which are not justified by the potential health risks presented because either the quantities are minute or the exposure is minimal.

Genencor Inc. (Ex. 8-51) stated:

In the proposed standard, all carcinogens are to be handled with the same level of control without regard to relative risk, quantity handled, concentration, physical properties (solid, liquid, vapor pressure) and method of use. This is not in accordance with the issuance of a performance standard or good industrial hygiene practices.

Los Alamos National Laboratory suggested that the proposed carcinogen provisions were appropriate for certain carcinogenic substances and certain use conditions but also pointed out the need for more flexibility as stated in the following excerpt:

Substances proven to be carcinogenic to humans or demonstrating high carcinogenic potency in animals should be controlled extremely well as proposed. However, the standard should allow for less stringent requirements where the operation involves only very dilute solutions (for example <0.1 or 0.01 percent, depending on the potency of the substance), or the substance has demonstrated carcinogenic potency only under high doses. (Ex. 8-20).

In addition to the concerns expressed in the comments discussed above, there were others that pointed out that there are numerous substances used in laboratories which present hazards both chronic and acute as severe as those presented by carcinogens. Dr. Emmett Barkley of the National Institutes of Health, for example, suggested that the regulatory approach taken in the proposal inappropriately implied that carcinogens may be the most hazardous of toxic substances to which laboratory workers may be exposed. He stated: "This is not the case. There are numerous chemicals whose acute toxicity is more hazardous than any currently regulated carcinogen." (Ex. 14, p. 4).

Similarly, Stephen R. Larson, Director of the Office of Environmental Health and Safety at Northeastern University suggested that the proposed standard overemphasized carcinogens and

underemphasized the hazards of acutely toxic substances. He stated: "Carcinogenicity or cancer-production is only one of many possible manifestations of harm from a toxic substance. Acute poisoning resulting in death or permanent injury are other manifestations which should be of equal concern." (Ex. 8-29).

The Environmental Protection Agency (Ex. 10-1) supported the special handling provisions for carcinogens but suggested the need for additional protective measures for highly toxic substances which were not necessarily carcinogenic.

The Standard Oil Company (Ex. 8-42) questioned the rationale for requiring special carcinogen provisions. With respect to the carcinogen provisions, Standard Oil commented as follows:

* * * [S]ince OSHA does not require these or similar stringent practices for chemical substances having other toxic effects such as teratogenicity, mutagenicity or extreme acute toxicity * * * OSHA apparently believes that the implementation of prudent laboratory practices will generally afford adequate protection from these hazards.

Finally, there were comments (see e.g., Exs. 8-19, 8-36, 8-42, 8-54, 8-66, 8-83, 8-107, 8-117, 8-118 and 10-9) which recommended that OSHA allow more flexibility in determining how best to handle particularly hazardous substances, including known carcinogens. Consider, for example, the comment submitted by Exxon Research and Engineering Company (Ex. 8-96). C.R. Lipuma, Manager of Technology Support commented:

* * * [I]t has been and still is in the best interest of research laboratories to take the approach of following good laboratory practices. This not only applies to potential carcinogens, but reproductive risk source materials and chemicals that have specific organ effects e.g., hepatotoxins, neurotoxins and the like. We believe the current emphasis on certain specific chemicals because they are suspect carcinogens, could result in employees in certain areas being over-cautious or even refusing work based on emotional response due to unnecessary extra attention. Simultaneously, these same employees may reduce their respect for other potentially hazardous material. We need to assure all employees follow procedures to protect themselves from the event of chemical exposures of any kind.

The comment from Hoffman-LaRoche Inc. (Ex. 8-111) emphasized the need for flexibility in determining when specific additional precautions are called for. The comment stated: "[S]ome degree of flexibility should be accorded to the employer in deciding the circumstances under which a regulated area is needed or whether a fume hood or other closed system is required."

After careful consideration of the evidence presented regarding the proposed approach to handling carcinogens, OSHA has made the following decisions with respect to the final standard:

(1) Narrowed the definition to "select carcinogen" to connote a category of chemicals where the evidence strongly indicates human carcinogenicity;

(2) Considered carcinogens in the context of laboratory work as only a subset of other particularly hazardous substances; and

(3) Allowed employers flexibility to assess the need for additional protective measures and to determine the appropriate precautions to effectively control exposures to particularly hazardous substances, including carcinogens.

Because the Hazard Communication Standard used the term, "carcinogen," in its definition of "hazardous chemical" (see appendix A of the HCS) and this standard tries to be consistent with the HCS definitions, it was necessary to distinguish the broad range of carcinogens covered in HCS from the narrower range covered in these special provisions of the laboratory standard. For this reason, the new term, "select carcinogen," was coined which refers to the subgroup of carcinogens for which there are special considerations in this standard.

In accordance with the recommendations in the comments regarding which carcinogens should be subject to special provisions, OSHA has designated four categories of carcinogens to be referred to as "select carcinogens" and therefore subject to special consideration in the employer's Chemical Hygiene Plan. For the purposes of this standard, "select carcinogen" includes any substance which meets one of the following criteria: (1) Is regulated by OSHA as a carcinogen or (2) is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or (3) is listed in Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer (IARC) (latest edition of Monograph).

In addition, a substance listed either by NTP under the category, "reasonably anticipated to be carcinogens," or listed by IARC in Group 2A or 2B shall be considered a select carcinogen only if it has "additional qualifications;" that is, has been shown to cause significant tumor incidence in experimental animals in accordance with any of the following criteria: (a) After inhalation

exposure of 6-7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m³ (b) after repeated skin application of less than 300 mg/kg of body weight) per week; or (c) after oral dosages of less than 50 (mg/kg of body weight) per day.

(Group 2A, according to IARC, is usually reserved for exposures for which there was at least limited evidence of carcinogenicity to humans. Group 2B, according to IARC, usually refers to the combination of sufficient evidence in animals and inadequate data in humans.)

Chemicals falling under IARC's Group 3 ("could not be classified as to their carcinogenicity in humans") are not considered as select carcinogens under this standard. This does not mean, however, that OSHA disputes the evidence linking these chemicals with carcinogenicity; it merely indicates that the Agency believes that the provisions of the Chemical Hygiene Plan outlined in the standard, if properly implemented, will adequately protect employee working with these substances.

If data corresponding to these criteria do not appear in the IARC or NTP documentation or in other existing literature for these substances, then they need not be treated as "select carcinogens" under this standard. However, it is the responsibility of the employer to determine whether such data exist.

The "additional qualifications" for substances listed by IARC and NTP for which definite carcinogenicity in humans has not been established were added in response to the many participants who were concerned that the definition as previously proposed would require special treatment for substances which had demonstrated only limited evidence of carcinogenicity. These criteria, designed to establish that a given substance exhibits moderate to high carcinogenic potency, are taken from the National Research Council's 1981 report, "Prudent Practices for Handling Hazardous Chemicals in Laboratories" (Ex. 7-13). OSHA included a discussion of these referenced criteria in the proposed standard (51 FR 26672). However, at the time OSHA felt their inclusion might require extensive literature searches or laboratory experiments which OSHA believed might be unreasonable where only small amounts of these substances were used. Certain comments, however, recommended that employers be allowed to make such evaluations (see e.g., Exs. 8-14, 8-19, 8-36, 8-118 and 10-9). Consequently, OSHA has decided that it would be more effective to allow

the individual laboratory to make the determination as to whether a substance listed under NTP's category, "reasonably anticipated to be carcinogens" and IARC Groups 2A or 2B meets the criteria of moderate to high carcinogenic potency before requiring the special considerations prescribed in the final rule.

In addition to narrowing the definition of carcinogen by using the new term "select carcinogen" in the final rule, the Agency has considered carefully comments that questioned the selection of carcinogens alone for special emphasis in the Chemical Hygiene Plan. On the basis of concerns expressed in the record, OSHA has decided not to confine the need for special consideration to carcinogens only. Therefore, OSHA has decided to add substances with high acute toxicity and reproductive toxins to select carcinogens as substances which will need special consideration in the Chemical Hygiene Plan.

Reproductive toxins may manifest themselves in lethal effects on the fertilized egg, developing embryo or fetus or teratogenic (malformation) effects in the fetus. In addition, certain reproductive toxins may cause infertility in females and males.

Substances with high acute toxicity such as hydrogen cyanide, hydrogen sulfide and nitrogen dioxide are included under the category of substances for which employers must consider the need for special precautions. Such substances may be fatal or cause damage to target organs as a result of a single exposure or exposures of short duration.

OSHA believes that employees should be made aware of the deleterious effects of these categories of substances discussed above through effective training which is reinforced where appropriate through written procedures in the employer's Chemical Hygiene Plan.

A number of commenters (Ex. 8-32, 8-35, 8-65, 8-66, and 8-87) objected to the inclusion of special mandatory provisions for designated substances such as carcinogens, stating that this would unnecessarily impinge on the employer's flexibility to deal with the hazards presented in their laboratories in the most expeditious manner. OSHA still believes that special consideration and emphasis may be needed when dealing with substances that are particularly hazardous. However, because of the wide degree of exposure and use conditions that may affect the actual degree of hazard to workers in a given situation, OSHA is providing the employer some added flexibility in the

final rule. Employers are required to focus their attention on certain types of substances and at least consider protective procedures for such substances explicitly in their Chemical Hygiene Plans, but the specific procedures which were required by the proposal are required by the final rule only where the employer has determined them to be appropriate. The provisions that must be included where deemed appropriate by the employer for work with select carcinogens, reproductive toxins and substances with a high degree of acute toxicity are: (1) The establishment of a designated area; (2) use of containment devices such as fume hoods or glove boxes; (3) procedures for safe removal of contaminated waste; and (4) decontamination procedures.

OSHA has replaced the term, "regulated area," with "designated" area in the final standard in response to comments that objected to the proposed provision. The definition of a regulated area as proposed meant a laboratory, an area of a laboratory or device such as a laboratory hood for which access is limited to persons who are aware of the hazards of the substances in use and the precautions that are necessary. In particular, Exs. 8-12, 8-24, and 8-86 voiced concern regarding this provision. Vista Chemical Company, for example, commented:

The establishment of regulated areas for work with carcinogens in laboratories and laboratory areas is impractical in many cases and inconsistent with the criteria used for the establishment of regulated areas in other standards. Laboratory fume hoods are seldom dedicated to one type of chemical use in manufacturing quality control labs . . . Use of carcinogenic material requiring the establishment of a regulated area is seldom continuous. (Ex. 8-86).

OSHA recognizes that even though the definition of a regulated area used in the proposed standard was significantly different from the way it is usually defined in other OSHA standards, it may have been interpreted the same. In OSHA's substance specific standards, regulated areas are required to be established where exposures to the substance exceed the PEL. In these instances an actual demarcation is implied to set these areas aside from other areas of the workplace and access is restricted to authorized personnel, thereby limiting the number of workers exposed. Typically, a medical surveillance program is required to be established and implemented for employees assigned to a regulated area. In other OSHA standards, such as those regulating the 13 Carcinogens, for

example, (see 29 CFR 1910.1003-1910.1016) employees working in regulated area needed to use special protective clothing and to shower before leaving the plant. OSHA recognizes that exposures of this magnitude are not typically found in laboratories, and given the nature of laboratory operations, restricted access to a work area or other restrictions may not be practical. However, OSHA believes that in the case of work involving select carcinogens, reproductive toxins and substances of high acute toxicity, especially in work areas where other less toxic chemicals are being used simultaneously, some method of limiting exposures and alerting all workers in the vicinity to the potential hazard may be warranted. Therefore, OSHA is using the less restrictive term, "designated area," in the final standard. A "designated area" differs from a regulated area in that the only duty associated with it is to post the area and assure that all employees working in the area are informed of the hazardous substances used there.

Under the final standard, fume hoods or equivalent containment devices are required to be considered by the employer for handling "select carcinogens," reproductive toxins, and substance with high acute toxicity only in certain circumstances. Circumstances that may require the use of containment devices include: the use of volatile substances, manipulations that may result in the generation of aerosols; and any manipulation, handling or reaction that may result in the uncontrollable release of the substance. (These were adopted from various safety guidelines including the "NIH Guidelines for the Laboratory Use of Chemical Carcinogens" and "Handling Chemical Carcinogens in the Laboratory Problems of Safety," IARC Scientific Publications No. 33, as well as from comments (see Exs. 8-66, 8-111 and 10-9) submitted to the record).

Because the "designated area" as used in this final standard is not as restrictive as the "regulated area" used in the proposal, and access is not limited, OSHA felt that it was essential to require employers to consider an additional provision for the protection of laboratory workers. The new provision requires the employer to consider whether decontamination procedures for the "designated area" are appropriate. These procedures would vary with the type of substance used. OSHA believes that such a provision may be necessary to minimize potential exposure to select carcinogens, reproductive toxins and

substances of high acute toxicity for other workers present in the designated area.

The provisions in the proposed standard which required employers to specify appropriate protective apparel to be worn by employees while working within a regulated area and specify appropriate hygiene practices have been deleted from the final rule with respect to designated areas since OSHA believes that this concern is already adequately covered under the general requirements of the Chemical Hygiene Plan.

The proposed Chemical Hygiene Plan also included provisions requiring the employer to evaluate laboratory operations and specify the criteria for operations that would need prior approval. Clearly, an employer might decide that certain operations involving highly toxic noncarcinogenic material or highly volatile toxic material needed prior approval and impose additional precautions at the time of such approval.

In addition, the final standard instructs employers to pay particular attention to the selection of controls for any other chemicals known to be extremely hazardous.

The employer's Chemical Hygiene Plan shall also make provision for employee training and information, medical consultation and examinations. However, for purposes of clarity these elements are included in the final standard under separate paragraphs and merely referenced in the CHP.

The final standard also requires that employers designate a Chemical Hygiene Officer to provide technical assistance in the development and administration of the Chemical Hygiene Plan. If deemed appropriate, the employer may establish a Chemical Hygiene Committee to assume this function. The designated individual(s) must be qualified by experience or training to carry out these responsibilities. However, OSHA intentionally did not define the skills needed to qualify as a Chemical Hygiene Officer since the requisite background experience and qualification would vary according to the complexity of the operation. Similarly, the final standard does not mandate what position or job classification the designated individual must hold in the employer's organizational structure. This is left entirely up to the employer. For example, the chemical hygiene responsibilities might be assigned to an individual presently serving as the safety officer, to a laboratory supervisor or to any other employee considered by the employer to be capable of carrying

out such responsibilities. There was only minimal comment in the record which specifically addressed the need for employers to assign an employee to develop and carry out the Chemical Hygiene Plan. Moreover, record evidence, including information in the Booz, Allen and Hamilton Laboratory Profile Study (Ex. 7-11), indicates that many employers currently have an employee assigned to safety and health responsibilities associated with their operation. OSHA believes that such actions attest to the recognized need that an effective employee protection program such as that required by the Chemical Hygiene Plan can best be achieved if coordinated and implemented by an individual assigned to carry out such functions.

There is further evidence in the record which suggests that even though laboratories have assigned individuals to oversee safety and health concerns, in many cases these individuals are not given the necessary authority to successfully carry out their responsibilities. See, for example, the testimony of Dr. Alan Todd, Director of Industrial Hygiene, Stewart-Todd Associates. Dr. Todd stated:

* * * [I]t is all too common to find that the safety officer who's typically a senior staff member has been saddled with the health and safety responsibility. At the same time, they are not given the authority to follow through in exercising reasonable control of laboratory materials and activities by their peers or those who work for them (Tr. 89).

The fact that OSHA is now requiring that employers designate a chemical hygiene officer should provide considerably more authority and responsibility to persons who function in this capacity.

Another concern expressed in the record was that the Chemical Hygiene Plan required by the Laboratory Standard duplicated many of the provisions of the Hazard Communication Standard. (See, e.g. Exs. 8-21, 8-32, 8-33, 8-35, 8-42, 8-47, 8-52, 8-54, 8-64, 8-85, 8-88, 8-96, 8-101, 8-105, and 8-112.) In particular, commenters questioned the need for a written Chemical Hygiene Plan in cases where laboratories associated with manufacturing operations have expanded the HCS program to all employees regardless of whether their work is in production or laboratory operations. Some commenters, among those cited above, requested that OSHA allow laboratories the option to comply with either the Laboratory Standard or the Hazard Communication Standard.

In response to this concern, OSHA believes that several points should be

considered. First, there is a basic difference between the intended objectives of the Laboratory Standard and those of the Hazard Communication Standard. The goal of the HCS is to communicate to employees the hazards of chemicals in the workplace. The employer's duties with respect to the HCS are directly related to the communication of information regarding hazards, including a description of any specific control measures that have been established to protect employees. The HCS, however, does not mandate the use of recommended control measures, but merely requires that information about appropriate control measures is communicated to the employees.

The Laboratory Standard, on the other hand, is designed to provide a comprehensive approach for the protection of laboratory workers which is more appropriate to laboratory conditions than compliance with the substance specific standards in 29 CFR part 1910, subpart Z. The Laboratory Standard requires that employers protect workers through the development and implementation of work practices and control measures expressly tailored to the individual laboratory workplace.

Both standards require that employees be trained regarding the hazards of the chemicals to which they may be exposed. For the most part, the training provisions required by the Laboratory Standard are identical to those of the HCS. There are, however, several additional training elements which are specific to the laboratory standard and the chemical hygiene plan in particular. For example, the employee shall be trained on the details of the Chemical Hygiene Plan which includes standard operating procedures, prior approval protocols, and procedures for handling select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity where appropriate. In addition, employees shall be informed of the location and availability of known reference material pertaining to the hazards, safe handling and disposal of chemicals in the laboratory. OSHA does not believe that these provisions which are felt to be essential for the protection of laboratory workers will result in undue compliance burdens.

Finally, wherever there may be duplication of any requirement, there is no need to perform the function twice. If an employer is complying with the Hazard Communication Standard, either by choice or necessity, his activities will automatically satisfy any identical requirement of this standard.

Paragraph (f) Training and Information

In the preamble to the proposed laboratory standard, OSHA proposed that the training and information provisions supersede those of the Hazard Communication Standard (HCS). (See 51 FR at 26661.) At the time the proposed standard was published, only laboratories in the manufacturing sector (SIC codes 20-39) were covered by the HCS training provisions. Since then, the Hazard Communication Standard was expanded to include laboratories and other businesses in non-manufacturing sectors as well. (52 FR 21852, August 24, 1987).

The training provisions of the proposed laboratory standard and the HCS are similar in intent; the major differences are summarized as follows: First, the proposed laboratory standard required that employees be trained only in areas related to health hazards. The HCS requires training for both physical and health hazards. Second, in lieu of specific training on chemical hazards, the proposed standard required that employees be informed of available references pertaining to the hazards and safe handling of toxic substances. The HCS explicitly requires that employees be trained in methods and observations to detect the presence or release of hazardous chemicals in the work area and protective measures including those instituted by the employer.

OSHA's rationale for the approach to training taken in the proposed laboratory standard was based in part on the evidence available at that time. This evidence indicated that, given the qualifications of laboratory personnel, the multiple chemicals typically used and changing procedures, the proposed training requirements were more relevant to laboratory operations than were the HCS provisions. OSHA, however, solicited comments as to whether the training section should more closely mirror the provisions of the HCS.

The training provisions of the proposed standard were supported in several of the comments submitted (Exs. 8-19, 8-36, 8-76, 8-107, 8-112, 8-118, and 10-17). For example, Dow Chemical Company stated:

OSHA asks for comments on whether the training and education section of this proposal should more closely mirror those of the HCS. We believe the performance oriented approach of this present proposal is more appropriate for laboratory personnel. As OSHA has been told many times, laboratory work is usually done by, or under the direction of highly trained personnel. The individuals usually have inquiring minds, and if informed where or how to get additional information on a substance, will seek it out.

Laboratory work can be extremely variable and can range from the more routine quality assurance work, which utilizes the same materials day after day, to basic research work where the materials may change daily. The HCS requires training and education each time a new hazard is introduced. In basic research type operations, this could be frequently. More general type training with a reference library or information source is preferable in achieving the desired goal of each individual feeling responsible for his or her own health and safety. (Ex. 8-112).

Similar support was offered by E.I. Du Pont De Nemours & Company:

The proposal as presented is well suited to laboratory operations. In many respects it parallels the HCS requirements. It also supplements the HCS requirements in order to respond to training needs specific to laboratories. Changes in the proposal to make the provisions identical to the requirements for industrial plants would render them less effective for laboratories. (EX. 8-19.)

In contrast, others (Exs. 8-9, 8-20, 8-23, 8-38, 8-66, 8-70, 8-75, 8-91, 8-97, 8-98, Tr. 135 and Tr. 234) suggested that the proposed provisions were not sufficient to effectively apprise workers of the hazards and precautions necessary to safely handle toxic substances in laboratories. For example, Dr. J. H. Carver commenting as a private citizen and Senior Genetic Toxicologist stated:

The training and education sections of the Proposed Chemical Hygiene Plan appear to be inadequate as outlined; they should adhere more closely to those provisions of the Hazard Communication Standard which requires training in the physical and health hazards of the chemicals in the work area. Information regarding available reference material is not sufficient (Ex. 8-9.)

In his testimony presented at the informal hearing, Norman Steere, consultant in laboratory safety, expressed the following views on the proposed training provisions:

I do not believe that the elements of the training program required by the proposed standard are sufficient to achieve effective communication about hazards and precautions for laboratory employees. Merely informing employees of the availability of reference material on the hazards and safe handling of toxic substances will not be effective unless the employee is highly motivated, and given on-the-job time to learn the necessary technical terminology and study the reference material. (Tr. 135).

Additional comments asserted that although many laboratory workers are trained in particular sciences, this fact does not obviate the need for specific training regarding hazards and safe handling of chemicals with which they work. Such views were reflected in the

comments of the Los Alamos National Laboratory:

*** We strongly believe that the training requirements should go beyond only informing employees of available reference materials on the hazards of chemicals in the work area, and should include actual training on the health and physical hazards of the chemicals. Although many laboratory personnel have advanced degrees and are highly competent in their fields of study, that does not make them expert in the hazards associated with chemicals. The hands-on work with chemicals will also often be performed by a technician whose training was primarily acquired on the job, and who has very little knowledge of the hazards that may be involved. *** Those with advanced degrees sometimes demonstrate a cavalier attitude towards the potential hazards, and it is important that laboratory employees receive training to recognize hazards. (Ex. 8-20).

Dr. Inara Brubaker, testifying on behalf of the American Chemical Society, agreed that laboratory workers were highly trained with respect to their particular scientific disciplines but pointed to a deficiency in the training provisions of the proposed standard. Dr. Brubaker testified:

Most laboratory workers are highly trained in the sciences, and when they are not, they are usually supervised by someone who is. *** This training has provided these professionals with a better background than most workers as to the hazards, exposures and appropriate means of protection in handling toxic substances. However, since safe work practice decisions are often made by the laboratory worker a comprehensive training program is the single most important aspect of worker protection. *** The proposed training and safety program falls short of informing laboratory employees of potential hazards to which they may be exposed. Merely informing workers of available reference material *** will not be sufficient to ensure employee health and safety. The ACS believes that the training *** should be at least as extensive as that required by the Hazard Communication Standard *** (Tr. 234-235).

In contrast, others objected to OSHA's proposal to have the training provisions of the laboratory standard supersede the provisions of the HCS. For example, Public Citizen stated:

*** While manufacturing workers (and soon all workers, when OSHA expands the HCS as it has been instructed to do so by the Court) have a right to be educated about the specific hazards of the chemicals they handle, laboratory workers will not have this right because the proposed standard would exempt laboratories from this facet of the HCS. In contrast, the proposal would merely require employees to be informed of available reference materials on laboratory hazards. Thus, meaningful training requirements are shipped away, and workers are left with what they already have—the opportunity for self-education. (Ex. 8-70).

After careful consideration of the complete record, OSHA has concluded that relevant portions of the HCS training and information section, with appropriate modification, should be incorporated into this standard.

The proposed training provisions may have relied too heavily on information which suggested that most laboratory personnel were already knowledgeable about the hazards related to the chemicals with which they work and the precautions necessary to protect themselves. Record comments (see e.g. Tr. 134-136, and Tr. 382) indicate this cannot be assumed to be the case for all laboratory workers. Even those with advanced degrees are not necessarily trained in the safety and health aspects associated with chemical exposures. OSHA also agrees with the recommendations in the record that laboratory employees should have the benefit of training in physical hazards. Physical hazards are often responsible for subsequent adverse health effects, e.g., explosions and fire could lead to the release of toxic fumes and vapors to which employees may be exposed. Moreover, the failure to require training concerning the potential physical hazards posed might encourage a false sense of security concerning the range of hazards presented.

In reaching its decision to incorporate the HCS training provisions into this final standard, OSHA also considered the experience that laboratories in the manufacturing sector have had with the Hazard Communication Standard. These laboratories have been subject to the HCS training provisions for several years. In addition, laboratories outside of the manufacturing sector were required to come into compliance with the HCS training provisions by May 23, 1988. OSHA believes that to introduce completely different requirements for employee training in the final laboratory standard might be unnecessarily confusing to employers and employees as well. With the framework of the training program already in place under the HCS, OSHA believes that the modifications to existing laboratory training programs necessary to accommodate the provisions added by the final laboratory standard are minimal but essential for an effective training program for laboratory workers.

Employee training shall include the methods and observations that may be used to detect the presence of hazardous chemicals in the work area including any measures that the employer has instituted; the physical and health hazards associated with chemicals in the work area and appropriate protection measures including

emergency procedures; and the details of the employer's Chemical Hygiene Plan.

Since this is a performance oriented standard, the amount and complexity of the training which must be implemented will vary with the complexity of the operations and the potential hazards.

The final standard therefore requires that employers provide employees with information and training so that they will be apprised of both physical and health hazards associated with hazardous chemicals present in their workplace. Such information and training is to be provided at the time of the employee's initial assignment and prior to assignments involving new hazardous chemicals or new exposure situations. The required training does not necessarily involve training for each specific chemical that the employee will use but rather the approach may be directed to classes or groups of hazardous chemicals. In addition, information to be communicated and made available to employees include the following: (1) The contents of the final standard and its appendices; (2) the employer's Chemical Hygiene Plan; (3) The PELs for OSHA regulated substances used in the work area and recommended exposure limits for other hazardous chemicals in the absence of an OSHA standard; (4) signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and (5) the availability of reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals. Reference material would include, but not be limited to, MSDSs that may be available from chemical suppliers.

Pertinent reference materials concerning the hazards, safe handling, storage and disposal of hazardous chemicals used in the laboratory are an essential part of an effective employee protection program. As required by the Hazard Communication Standard, such hazard information is to be provided by the material safety data sheet that accompanies the shipment of the chemical. However, in the event such information is not received or is incomplete, or in cases where the chemical is generated by the laboratory, additional reference material may be necessary. The final standard requires that where reference material, including material safety data sheets, are known to be available, the employer shall inform employees of their location and availability. The standard places no restrictions on the form in which reference materials should be kept, and some employers may wish to utilize

computer technology. This format is acceptable as long as employees are aware of the procedures necessary to access the information from this source.

Paragraph (g) Medical Consultation and Medical Examinations

At the time the standard was proposed, OSHA's available information indicated that, given the multiple chemicals used and the unpredictable exposure situations typical of most laboratory operations, exposure monitoring was not practical. Additionally, routine medical surveillance was indicated to be prohibitively expensive and have little value because of the wide variety of substances to which workers were exposed and the difficulty in identifying indicators of adverse health effects.

OSHA, however, recognized that the potential for overexposure still existed and attempted to strike a balance in the proposal between adequate medical monitoring and practical utility. The proposal required employers to provide employees with an exposure evaluation in cases where there was reason to believe overexposure to a toxic substance had taken place. The exposure evaluation would be conducted by the Chemical Hygiene Officer and would provide an assessment of the conditions associated with the suspected overexposure. Among the factors to be considered in conducting an exposure evaluation were the chemical and physical properties of the substance involved, the quantity in use, the potential for overexposure associated with the operation involved and an estimation of the duration of exposure (51 FR at 26673). If the exposure evaluation indicated that an overexposure was likely to have occurred, the affected employee would be given an opportunity for medical consultation. The consultation included physician review of the exposure evaluation results and a conference with the affected employee, if necessary, to determine the need for medical examinations in a particular instance and, if indicated, follow-up medical procedures.

OSHA's proposed approach to medical protection for laboratory workers was supported by several participants in their response to this issue. For example, Dr. W. Emmett Barkley, former Director of the Division of Safety at the National Institutes of Health testified as follows:

The provisions for exposure evaluation and medical consultation are sensible for most compounds and uses in the laboratory, and they reflect the current state of knowledge

regarding the efficacy of medical surveillance initiatives within the laboratory setting.

Overt exposures to toxic substances should initiate thorough evaluation to assess the degree of exposure. If it is determined that an overexposure has occurred, it is imperative that employees be provided with medical consultations and follow-up treatments, as necessary. (Tr. 111).

Further support was presented in the comment submitted by the Chemical Manufacturers Association (CMA):

We agree fully with the proposal that each chemical hygiene plan should provide for medical consultation in all cases where an exposure evaluation indicates the likelihood of overexposure. Such consultations should be followed up by medical examinations or medical surveillance if recommended as a result of the medical consultation. (Ex. 8-65).

Other comments agreed with parts of OSHA's exposure evaluation/medical proposal. For example, the comment submitted by Vulcan Chemicals stated:

While the provision for an exposure evaluation for employees who may have been overexposed to a toxic substance is a reasonable requirement, the requirement for a mandatory medical consultation for such employees is ill conceived. The exceedance of the OSHA permissible exposure limit or the ACGIH TLV does not automatically place an employee at such a risk that medical consultation is necessary * * * The PEL or TLV describes an exposure level to which an employee may be exposed for a working lifetime without harmful effects. Thus, the mere exceedance of this level may not result in a harmful effect. (Ex. 8-68).

However, other comments related to this issue recommended that OSHA require employers to institute a more comprehensive approach to ensure that employees have the full benefit of an appropriate medical protection program. See, for example, Exs. 8-15, 8-23, 8-38, 8-50, 8-70, 8-75, 8-76, and Tr. 48 which share the concerns expressed by the U.S. Department of Agriculture:

The proposed rule includes provisions for an exposure evaluation and medical consultation whenever an employee may have been overexposed to a toxic substance * * * However, the proposed rule lacks a preventive health orientation by linking these provisions to only incidents of suspected or actual over exposure to toxic substances * * * (Ex. 10-6).

The requirement for an exposure evaluation as a means to trigger medical consultation for employees was criticized by several participants. For example, Maureen Hamilton, CIH, Director of Environmental Health Sciences at NHS, Inc. stressed the impracticality of this provision. She stated:

The use of "exposure evaluations" when an employee feels he or she has been overexposed to a toxic substance is

impractical. Trying to recreate a situation after the fact is virtually impossible and always open to debate. (Ex. 8-84).

Dr. Daniel Teitelbaum, Director of Medical Toxicology at Denver Clinic Medical Centers and expert OSHA witness was opposed to the exposure evaluation concept for different reasons. Dr. Teitelbaum testified as follows:

I do not believe that employees should be required to be approved for a visit to a physician by a non-health professional when a potentially serious exposure to a chemical hazard is believed by the employee to have occurred. On the contrary, the employee should be encouraged to seek consultation from a physician or occupational health nurse at once if there is a reasonable belief that an exposure to a toxic substance has taken place * * * It is often not appreciated that following exposure to many chemicals, there is a golden period during which appropriate treatment may prevent the occurrence of serious and life-threatening illness. If one delays treatment for these injuries until after the symptoms begin, the patient may suffer increased morbidity or die because treatment is given too late. (Dr. Daniel Teitelbaum, Tr. (43-44).)

After careful consideration of the information submitted with respect to the exposure evaluation as a mechanism to determine the need for medical consultation for affected employees, OSHA agrees that this approach would rely too heavily on subjective judgment. As Dr. Teitelbaum pointed out in his testimony (Tr. 43-44) on this issue, a non health professional such as the Chemical Hygiene Officer may not necessarily recognize the nuances that influence appropriate judgment calls. For these reasons, this approach is not used in the final standard.

Some commenters recommended a more comprehensive approach to medical coverage for laboratory workers than that outlined in the proposed standard, citing the benefits of baseline medical examinations, periodic reexaminations and medical surveillance (see e.g. Exs. 8-15, 8-22, 8-38, 8-70 and 8-76). However, it is important to note the experience of a major research center, the National Institutes of Health. According to Dr. W. Emmett Barkley, former Director of the Division of Safety, in the past, the NIH applied the "kitchen sink" approach in its efforts to implement a medical program for laboratory workers.

* * * [F]or 10 years we had what I will call a "kitchen sink" approach to medical surveillance. Annually, we provided everything we thought was relevant to physical examinations. We recorded every compound for which people used in their work, both viruses and chemicals, and we evaluated this after a six-year use period, and

found that it was not effective as a means for addressing worker safety. The resources that we put into that could more effectively be used to monitoring the processes by which people carried out their work and educating and enforcing practices more vigorously. (Tr. 120).

Dr. Barkley subsequently described the role of medical consultation as used at the NIH:

We do, however, provide medical consultation for any situation where an overt exposure to a chemical or biological system occurs, whether it be through inhalation, skin contact, self-inoculation or what have you. We feel that this is very, very important, not only to maintain a record of the event, but to see whether there are processes or procedures that we could follow to see whether there was the degree of exposure, and we also look at it from the standpoint of how we might prevent this occurrence again. (Tr. 121).

In deciding the type of medical program that would be appropriate for laboratory workers, it is important to keep in mind the nature of exposure conditions in a typical laboratory covered by this standard. Typically, chemicals used and procedures performed change frequently. Moreover, according to information in the record, it is not always known in advance which chemicals will be involved in a laboratory procedure. (See, for example, Ex. 3-72 and Ex. 7-2.) OSHA believes that these conditions seriously confound the effectiveness of a medical surveillance program. Similarly, OSHA is not convinced, given the unpredictable array of chemicals in laboratories, that general baseline examinations would provide meaningful correlation in the event of future adverse exposures unless certain conditions are known in advance.

In reaching this conclusion, OSHA does not suggest that medical provisions are not needed under any circumstances to protect laboratory workers. The difficulty arises in establishing a rational approach as to when such provisions should apply. Clearly, if an employee exhibits signs or symptoms related to exposure to a hazardous chemical or if an employee is subjected to events such as spills, leaks, explosions or other unexpected occurrences where there is a likelihood of exposure to hazardous chemicals, that employee should be afforded an opportunity to receive appropriate medical attention.

The final laboratory standard provides for medical attention under these circumstances. Specifically, the standard requires that employers provide employees with an opportunity to receive appropriate medical

examinations whenever the employee exhibits signs or symptoms associated with exposure to a hazardous chemical. The employer shall also provide employees with an opportunity to receive a medical consultation whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a significant exposure to a hazardous chemical. The medical consultation is provided for the purpose of determining the need for a medical examination. The employee shall be afforded an opportunity to receive any examinations recommended by the physician. All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided at a reasonable time and place without cost to the employee.

OSHA believes the situations described above should be covered as a minimum in any medical program designed for laboratory workers. However, beyond the circumstances just mentioned and on the basis of the rulemaking record, OSHA has provided additional protection in the event that workplace exposures routinely exceed those extremely small exposures upon which this standard was predicated. In the earlier discussion in this preamble concerning Employee Exposure Determination (paragraph (d)), exposure conditions are described under which the employer must comply with the medical and monitoring provisions of a relevant standard that are triggered by exposure over an action level (or PEL where there is no action level). Those conditions involve routine exposure levels in excess of an action level (or PEL in the absence of an action level) for an OSHA regulated substance for which there are monitoring and medical surveillance requirements. The result of the addition of this provision is that if there appears to be an identifiable condition in terms of overexposure, *i.e.*, exposure levels above the action level (or in the absence of an action level, the PEL), signs or symptoms of exposure, or the occurrence of an unusual event such as an explosion, leak or spill, then medical attention will be provided.

In view of the foregoing evidence OSHA believes that the provision of the final standard with respect to employee medical protection is sound and adequately protective of employee health. It is also reasonably necessary and appropriate to achieve this goal.

Paragraph (h). Hazard Identification

OSHA's proposed laboratory standard did not include special provisions for labeling. However, OSHA

solicited comments regarding the need for such provisions. (51 FR at 26676).

Among those commenters who responded to this issue, several (see Exs. 8-48, 8-79, 8-106 and 8-108) specifically recommended that OSHA retain for this standard the labeling requirements of HCS as they pertain to laboratories. OSHA believes that this action is appropriate. OSHA also recognizes that labeling practices may best be implemented by the individual employer as part of the Chemical Hygiene Plan.

Therefore, the requirements of OSHA's Hazard Communication Standard concerning retention of labels and material safety data sheets accompanying incoming shipments of hazardous chemicals have been incorporated into this standard. This action does not represent an increased obligation on employers. Employers are to ensure that labels on incoming containers of hazardous chemicals are not removed or defaced. In addition, material safety data sheets which accompany incoming shipments of hazardous chemicals are to be maintained and made accessible to employees.

To avoid any confusion which could arise regarding hazard identification relating to the Hazard Communication Standard as distinct from that relating to this standard, OSHA has added three clarifying statements regarding laboratory-generated chemical substances. First, if a chemical substance whose chemical composition is known is produced in the laboratory for its own exclusive use, OSHA requires that available hazard information be provided to employees who may be exposed to the substance. MSDS and label preparations as required under the Hazard Communication Standard do not apply since, still qualifying under the laboratory use and laboratory scale definitions, the laboratory remains covered by this standard and is thus exempted from those requirements of the HCS.

Second, employers who produce a chemical byproduct whose composition is unknown shall make the assumption that the substance is hazardous and require that it be handled according to the Chemical Hygiene Plan in paragraph (e) which provides for appropriate employee protection for hazardous chemicals. OSHA believes that in this particular case, if the hazardous properties of a chemical substance are unknown, the most prudent approach to employee protection is to handle the material as if it were known to be

hazardous. By following this approach, the employer will not be required to conduct literature searches or perform actual tests to evaluate the hazard.

Finally, the standard clarifies the employer's responsibility where a chemical is produced in the laboratory and shipped to another user outside of the laboratory. With respect to the substance produced, the employer has become a manufacturer and therefore is subject to all the relevant provisions of the Hazard Communication Standard including requirements for the development of a material safety data sheet and labeling. However, if manufacturing is not the laboratory's principal concern, the laboratory standard remains in effect for those activities unrelated to the manufacturing operations.

Regarding shipment of waste materials, the Hazard Communication requirement will not apply in any case. Any requirement under EPA regulations regarding waste disposal will, of course, continue to apply. However, OSHA regards waste disposal by a laboratory to be a normal laboratory function. Thus, the Hazard Communication Standard will not apply as it would in the case of a substance which would be produced for and shipped to another organization.

Paragraph (i). Use of Respirators

This provision requires that any use of respirators which is necessary to maintain exposures below PELs must comply with the requirements in the respiratory protection standard, 29 CFR 1910.134. Consistent with other OSHA health standards, any necessary respiratory equipment must be provided without cost to employees. These provisions do not impose any new requirements on laboratory employers, but are included here to remind the employer of the existing compliance duty.

Paragraph (j). Recordkeeping

Section 8(c) of the Act authorizes the promulgation of regulations to make, keep and preserve such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for the development of information regarding the causes and prevention of occupational illnesses. The information currently before OSHA indicates that exposure monitoring and medical records prescribed herein are necessary and appropriate to both the enforcement of the standard and the development of information regarding the causes and prevention of workplace illnesses.

OSHA received only minimal comment regarding the recordkeeping requirements included in the proposed standard. One comment, (Ex. 8-104), requested clarification as to whether all medical records or just those pertaining to the overexposure were to be retained. OSHA believes that this point is clarified in the final standard in that any medical and exposure record created in connection with the standard shall be kept in accordance with 29 CFR 1910.20. Section 1910.20 is the generic standard for access to employee medical and exposure records. Section 1910.20 provides that records must be kept for the duration of employment plus 30 years and has detailed provisions for the transfer of records. OSHA has access to both medical and exposure records, subject to the Agency rules at 29 CFR 1913.10. An extensive discussion of the provisions and rationale for § 1910.20 can be found in the *Federal Register* of September 29, 1988 (53 FR 38140).

Paragraph (k). Effective Date

The final rule becomes effective 90 days following publication in the *Federal Register*. The standard provides a start-up date. The completion of preparation and implementation of the Chemical Hygiene Plan is not required until one year after the publication date.

The Agency received only minimal comments on the effective date and start-up date included in the proposed standard. Several commenters agreed that the time intervals were appropriate, (see, e.g., Exs. 8-38 and 8-65). Others, however, felt that a longer start-up interval of up to two years was necessary, but provided no persuasive arguments (Exs. 8-33, 8-53, 8-91, and 8-111).

OSHA has carefully reviewed the provisions of the standard in terms of the length of time that would be required for employers to come into full compliance. Many employers have already instituted or are in the process of developing employee protection programs for which only minor modifications may be necessary to achieve compliance with this standard. OSHA believes that the effective date and start-up date set by the standard are reasonable and sufficient for all affected employers, including those beginning a new program, to become familiar with the contents of the preamble, standard and appendices and to complete and implement the Chemical Hygiene Plan.

Paragraph (l). Appendices

Two appendices are included in the final standard. The primary purpose of

these appendices is to provide guidance to the employer in developing and implementing an appropriate Chemical Hygiene Plan. Appendix A is a distillation of pertinent parts of "Prudent Practices for Handling Hazardous Chemicals in Laboratories." Appendix B is a list of references which may be helpful to the employer in developing a Chemical Hygiene Plan. None of the statements in the appendices should be construed as establishing any mandatory requirements which are not otherwise imposed by the standard. Minor changes have been made in some instances to the appendices in the final rule. These changes reflect certain suggestions made by commenters (see, e.g., Exs. 8-19, 8-107) to improve the clarity of the information presented.

VII. Federalism and State Plan Applicability

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

In short, there is a clear national problem related to occupational safety and health for employees exposed to hazardous chemicals in laboratories. Those States which have elected to participate under section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while

ensuring that their standards are at least as effective as the Federal standard.

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of publication of a final rule. The States are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. For New York and Connecticut, plans cover only state and local government employees. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these States.

VIII. Authority and Signature

This document was prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Pursuant to sections 6(b) and 8(c) and 8(g)(2) of the Act, OSHA hereby amends 29 CFR part 1910 by adding a new § 1910.1450 as set forth below.

List of Subjects in 29 CFR Part 1910

Laboratories, Occupational safety and health.

Signed at Washington, DC, this 22nd day of January 1990.

Gerard F. Scannell,

Assistant Secretary for Occupational Safety and Health.

Part 1910 of title 29 of the Code of Federal Regulation (CFR) is hereby amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for part 1910, subpart Z is amended by adding the following citation at the end. (Citation which precedes asterisk indicates general rulemaking authority.)

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR part 1911.

* * * Section 1910.1450 is also issued under sec. 6(b), 8(c) and 8(g)(2), Pub. L. 91-596, 84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657.

2. Section 1910.1450 is added to subpart Z, part 1910 to read as follows:

§ 1910.1450 Occupational exposure to hazardous chemicals in laboratories.

(a) *Scope and application.* (1) This section shall apply to all employers

engaged in the laboratory use of hazardous chemicals as defined below.

(2) Where this section applies, it shall supersede, for laboratories, the requirements of all other OSHA health standards in 29 CFR part 1910, subpart Z, except as follows:

(i) For any OSHA health standard, only the requirement to limit employee exposure to the specific permissible exposure limit shall apply for laboratories, unless that particular standard states otherwise or unless the conditions of paragraph (a)(2)(iii) of this section apply.

(ii) Prohibition of eye and skin contact where specified by any OSHA health standard shall be observed.

(iii) Where the action level (or in the absence of an action level, the permissible exposure limit) is routinely exceeded for an OSHA regulated substance with exposure monitoring and medical surveillance requirements, paragraphs (d) and (g)(1)(ii) of this section shall apply.

(3) This section shall not apply to:

(i) Uses of hazardous chemicals which do not meet the definition of laboratory use, and in such cases, the employer shall comply with the relevant standard in 29 CFR part 1910, subpart Z, even if such use occurs in a laboratory.

(ii) Laboratory uses of hazardous chemicals which provide no potential for employee exposure. Examples of such conditions might include:

(A) Procedures using chemically-impregnated test media such as Dip-and-Read tests where a reagent strip is dipped into the specimen to be tested and the results are interpreted by comparing the color reaction to a color chart supplied by the manufacturer of the test strip; and

(B) Commercially prepared kits such as those used in performing pregnancy tests in which all of the reagents needed to conduct the test are contained in the kit.

(b) *Definitions.*

"Action level" means a concentration designated in 29 CFR part 1910 for a specific substance, calculated as an eight (8)-hour time-weighted average, which initiates certain required activities such as exposure monitoring and medical surveillance.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Carcinogen" (see "select carcinogen").

"Chemical Hygiene Officer" means an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development

and implementation of the provisions of the Chemical Hygiene Plan. This definition is not intended to place limitations on the position description or job classification that the designated individual shall hold within the employer's organizational structure.

"Chemical Hygiene Plan" means a written program developed and implemented by the employer which sets forth procedures, equipment, personal protective equipment and work practices that (i) are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace and (ii) meets the requirements of paragraph (e) of this section.

"Combustible liquid" means any liquid having a flashpoint at or above 100 °F (37.8 °C), but below 200 °F (93.3 °C), except any mixture having components with flashpoints of 200 °F (93.3 °C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"Compressed gas" means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 °F (21.1 °C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 °F (54.4 °C) regardless of the pressure at 70 °F (21.1 °C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100 °F (37.8 °C) as determined by ASTM D-323-72.

"Designated area" means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers or failure of control equipment which results in an uncontrolled release of a hazardous chemical into the workplace.

"Employee" means an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments.

"Explosive" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"Flammable" means a chemical that falls into one of the following categories:

(i) "Aerosol, flammable" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a

flame protection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening:

(ii) "*Gas, flammable*" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.

(iii) "*Liquid, flammable*" means any liquid having a flashpoint below 100 °F (37.8 °C), except any mixture having components with flashpoints of 100 °F (37.8 °C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "*Solid, flammable*" means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"*Flashpoint*" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 (ASTM D 56-79))—for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 °F (37.8 °C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 (ASTM D 93-79))—for liquids with a viscosity equal to or greater than 45 SUS at 100 °F (37.8 °C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

"*Hazardous chemical*" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes, or mucous membranes.

Appendices A and B of the Hazard Communication Standard (29 CFR 1910.1200) provide further guidance in defining the scope of health hazards and determining whether or not a chemical is to be considered hazardous for purposes of this standard.

"*Laboratory*" means a facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

"*Laboratory scale*" means work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safely manipulated by one person. "Laboratory scale" excludes those workplaces whose function is to produce commercial quantities of materials.

"*Laboratory-type hood*" means a device located in a laboratory, enclosure on five sides with a moveable sash or fixed partial enclosed on the remaining side; constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory; and allows chemical manipulations to be conducted in the enclosure without insertion of any portion of the employee's body other than hands and arms.

Walk-in hoods with adjustable sashes meet the above definition provided that the sashes are adjusted during use so that the airflow and the exhaust of air contaminants are not compromised and employees do not work inside the enclosure during the release of airborne hazardous chemicals.

"*Laboratory use of hazardous chemicals*" means handling or use of such chemicals in which all of the following conditions are met:

(i) Chemical manipulations are carried out on a "laboratory scale;"

(ii) Multiple chemical procedures or chemicals are used;

(iii) The procedures involved are not part of a production process, nor in any way simulate a production process; and

(iv) "Protective laboratory practices and equipment" are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

"*Medical consultation*" means a consultation which takes place between an employee and a licensed physician for the purpose of determining what medical examinations or procedures, if any, are appropriate in cases where a significant exposure to a hazardous chemical may have taken place.

"*Organic peroxide*" means an organic compound that contains the bivalent —O—O— structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"*Oxidizer*" means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"*Physical hazard*" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"*Protective laboratory practices and equipment*" means those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous chemicals.

"*Reproductive toxins*" means chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).

"*Select carcinogen*" means any substance which meets one of the following criteria:

(i) It is regulated by OSHA as a carcinogen; or

(ii) It is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or

(iii) It is listed under Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer Monographs (IARC) (latest editions); or

(iv) It is listed in either Group 2A or 2B by IARC or under the category, "reasonably anticipated to be

carcinogens" by NTP, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:

(A) After inhalation exposure of 6-7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m³;

(B) After repeated skin application of less than 300 (mg/kg of body weight) per week; or

(C) After oral dosages of less than 50 mg/kg of body weight per day.

"Unstable (reactive)" means a chemical which is the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks, pressure or temperature.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

(c) *Permissible exposure limits.* For laboratory uses of OSHA regulated substances, the employer shall assure that laboratory employees' exposures to such substances do not exceed the permissible exposure limits specified in 29 CFR part 1910, subpart Z.

(d) *Employee exposure determination—(1) Initial monitoring.* The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

(2) *Periodic monitoring.* If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

(3) *Termination of monitoring.* Monitoring may be terminated in accordance with the relevant standard.

(4) *Employee notification of monitoring results.* The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting results in an appropriate location that is accessible to employees.

(e) *Chemical hygiene plan—General.* (Appendix A of this section is non-mandatory but provides guidance to assist employers in the development of the Chemical Hygiene Plan.) (1) Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

(i) Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory and

(ii) Capable of keeping exposures below the limits specified in paragraph (c) of this section.

(2) The Chemical Hygiene Plan shall be readily available to employees, employee representatives and, upon request, to the Assistant Secretary.

(3) The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection:

(i) Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

(ii) Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

(iii) A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

(iv) Provisions for employee information and training as prescribed in paragraph (f) of this section;

(v) The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

(vi) Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

(vii) Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer and, if appropriate, establishment of a Chemical Hygiene Committee; and

(viii) Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following provisions which shall be included where appropriate:

(A) Establishment of a designated area;

(B) Use of containment devices such as fume hoods or glove boxes;

(C) Procedures for safe removal of contaminated waste; and

(D) Decontamination procedures.

(4) The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

(f) *Employee information and training.*

(1) The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

(2) Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

(3) *Information.* Employees shall be informed of:

(i) The contents of this standard and its appendices which shall be made available to employees;

(ii) The location and availability of the employer's Chemical Hygiene Plan;

(iii) The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;

(iv) Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and

(v) The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets received from the chemical supplier.

(4) *Training.* (i) Employee training shall include:

(A) Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(B) The physical and health hazards of chemicals in the work area; and

(C) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(ii) The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

(g) *Medical consultation and medical examinations.* (1) The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:

(i) Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

(ii) Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.

(iii) Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.

(2) All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

(3) *Information provided to the physician.* The employer shall provide the following information to the physician:

(i) The identity of the hazardous chemical(s) to which the employee may have been exposed;

(ii) A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and

(iii) A description of the signs and symptoms of exposure that the employee is experiencing, if any.

(4) *Physician's written opinion.* (i) For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:

(A) Any recommendation for further medical follow-up;

(B) The results of the medical examination and any associated tests;

(C) Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous chemical found in the workplace; and

(D) A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

(ii) The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.

(h) *Hazard identification.* (1) With respect to labels and material safety data sheets:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.

(2) The following provisions shall apply to chemical substances developed in the laboratory:

(i) If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.

(ii) If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.

(iii) If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.

(i) *Use of respirators.* Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.

(j) *Recordkeeping.* (1) The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

(2) The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.20.

(k) *Dates.*—(1) *Effective date.* This section shall become effective May 1, 1990.

(2) *Start-up dates.* (i) Employers shall have developed and implemented a written Chemical Hygiene Plan no later than January 31, 1991.

(ii) Paragraph (a)(2) of this section shall not take effect until the employer has developed and implemented a written Chemical Hygiene Plan.

(l) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A to § 1910.1450—National Research Council Recommendations Concerning Chemical Hygiene in Laboratories (Non-Mandatory)

Table of Contents

Foreword

Corresponding Sections of the Standard and This Appendix

A. General Principles

1. Minimize all Chemical Exposures
2. Avoid Underestimation of Risk
3. Provide Adequate Ventilation
4. Institute a Chemical Hygiene Program
5. Observe the PELs and TLVs

B. Responsibilities

1. Chief Executive Officer
2. Supervisor of Administrative Unit
3. Chemical Hygiene Officer
4. Laboratory Supervisor
5. Project Director
6. Laboratory Worker

C. The Laboratory Facility

1. Design
2. Maintenance
3. Usage
4. Ventilation

D. Components of the Chemical Hygiene Plan

1. Basic Rules and Procedures
2. Chemical Procurement, Distribution, and Storage
3. Environmental Monitoring
4. Housekeeping, Maintenance and Inspections
5. Medical Program
6. Personal Protective Apparel and Equipment
7. Records
8. Signs and Labels
9. Spills and Accidents
10. Training and Information
11. Waste Disposal

E. General Procedures for Working With Chemicals

1. General Rules for all Laboratory Work with Chemicals
2. Allergens and Embryotoxins

3. Chemicals of Moderate Chronic or High Acute Toxicity
4. Chemicals of High Chronic Toxicity
5. Animal Work with Chemicals of High Chronic Toxicity

F. Safety Recommendations

G. Material Safety Data Sheets

Foreword

As guidance for each employer's development of an appropriate laboratory Chemical Hygiene Plan, the following non-mandatory recommendations are provided. They were extracted from "Prudent Practices for Handling Hazardous Chemicals in Laboratories" (referred to below as "Prudent Practices"), which was published in 1981 by the National Research Council and is available from the National Academy Press, 2101 Constitution Ave., NW., Washington DC 20418.

"Prudent Practices" is cited because of its wide distribution and acceptance and because of its preparation by members of the laboratory community through the sponsorship of the National Research Council. However, none of the recommendations given here will modify any requirements of the laboratory standard. This Appendix merely presents pertinent recommendations from "Prudent Practices", organized into a form convenient for quick reference during operation of a laboratory facility and during development and application of a Chemical Hygiene Plan. Users of this appendix should consult "Prudent Practices" for a more extended presentation and justification for each recommendation.

"Prudent Practices" deals with both safety and chemical hazards while the laboratory standard is concerned primarily with chemical hazards. Therefore, only those recommendations directed primarily toward control of toxic exposures are cited in this appendix, with the term "chemical hygiene" being substituted for the word "safety". However, since conditions producing or threatening physical injury often pose toxic risks as well, page references concerning major categories of safety hazards in the laboratory are given in section F.

The recommendations from "Prudent Practices" have been paraphrased, combined, or otherwise reorganized, and headings have been added. However, their sense has not been changed.

Corresponding Sections of the Standard and this Appendix

The following table is given for the convenience of those who are developing a Chemical Hygiene Plan which will satisfy the requirements of paragraph (e) of the standard. It indicates those sections of this appendix which are most pertinent to each of the sections of paragraph (e) and related paragraphs.

Paragraph and topic in laboratory standard	Relevant appendix section
(e)(3)(i) Standard operating procedures for handling toxic chemicals.	C, D, E
(e)(3)(ii) Criteria to be used for implementation of measures to reduce exposures.	D
(e)(3)(iii) Fume hood performance.....	C4b
(e)(3)(iv) Employee information and training (including emergency procedures).	D10, D9
(e)(3)(v) Requirements for prior approval of laboratory activities.	E2b, E4b
(e)(3)(vi) Medical consultation and medical examinations.	D5, E4f
(e)(3)(vii) Chemical hygiene responsibilities.	B
(e)(3)(viii) Special precautions for work with particularly hazardous substances.	E2, E3, E4

In this appendix, those recommendations directed primarily at administrators and supervisors are given in sections A-D. Those recommendations of primary concern to employees who are actually handling laboratory chemicals are given in section E. (Reference to page numbers in "Prudent Practices" are given in parentheses.)

A. General Principles for Work with Laboratory Chemicals

In addition to the more detailed recommendations listed below in sections B-E, "Prudent Practices" expresses certain general principles, including the following:

1. *It is prudent to minimize all chemical exposures.* Because few laboratory chemicals are without hazards, general precautions for handling all laboratory chemicals should be adopted, rather than specific guidelines for particular chemicals (2, 10). Skin contact with chemicals should be avoided as a cardinal rule (198).

2. *Avoid underestimation of risk.* Even for substances of no known significant hazard, exposure should be minimized; for work with substances which present special hazards, special precautions should be taken (10, 37, 38). One should assume that any mixture will be more toxic than its most toxic component (30, 103) and that all substances of unknown toxicity are toxic (3, 34).

3. *Provide adequate ventilation.* The best way to prevent exposure to airborne substances is to prevent their escape into the working atmosphere by use of hoods and other ventilation devices (32, 198).

4. *Institute a chemical hygiene program.* A mandatory chemical hygiene program designed to minimize exposures is needed; it should be a regular, continuing effort, not merely a standby or short-term activity (6, 11). Its recommendations should be followed in academic teaching laboratories as well as by full-time laboratory workers (13).

5. *Observe the PELs, TLVs.* The Permissible Exposure Limits of OSHA and the Threshold Limit Values of the American Conference of Governmental Industrial Hygienists should not be exceeded (13).

B. Chemical Hygiene Responsibilities

Responsibility for chemical hygiene rests at all levels (6, 11, 21) including the:

1. *Chief executive officer*, who has ultimate responsibility for chemical hygiene within the institution and must, with other administrators, provide continuing support for institutional chemical hygiene (7, 11).

2. *Supervisor of the department or other administrative unit*, who is responsible for chemical hygiene in that unit (7).

3. *Chemical hygiene officer(s)*, whose appointment is essential (7) and who must:

(a) Work with administrators and other employees to develop and implement appropriate chemical hygiene policies and practices (7);

(b) Monitor procurement, use, and disposal of chemicals used in the lab (8);

(c) See that appropriate audits are maintained (8);

(d) Help project directors develop precautions and adequate facilities (10);

(e) Know the current legal requirements concerning regulated substances (50); and

(f) Seek ways to improve the chemical hygiene program (8, 11).

4. *Laboratory supervisor*, who has overall responsibility for chemical hygiene in the laboratory (21) including responsibility to:

(a) Ensure that workers know and follow the chemical hygiene rules, that protective equipment is available and in working order, and that appropriate training has been provided (21, 22);

(b) Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment (21, 171);

(c) Know the current legal requirements concerning regulated substances (50, 231);

(d) Determine the required levels of protective apparel and equipment (156, 160, 162); and

(e) Ensure that facilities and training for use of any material being ordered are adequate (215).

5. *Project director or director of other specific operation*, who has primary responsibility for chemical hygiene procedures for that operation (7).

6. *Laboratory worker*, who is responsible for:

(a) Planning and conducting each operation in accordance with the institutional chemical hygiene procedures (7, 21, 22, 230); and

(b) Developing good personal chemical hygiene habits (22).

C. The Laboratory Facility

1. *Design.* The laboratory facility should have:

(a) An appropriate general ventilation system (see C4 below) with air intakes and exhausts located so as to avoid intake of contaminated air (194);

(b) Adequate, well-ventilated stockrooms/storerooms (218, 219);

(c) Laboratory hoods and sinks (12, 162);

(d) Other safety equipment including eyewash fountains and drench showers (162, 169); and

(e) Arrangements for waste disposal (12, 240).

2. *Maintenance.* Chemical-hygiene-related equipment (hoods, incinerator, etc.) should undergo continuing appraisal and be modified if inadequate (11, 12).

3. *Usage.* The work conducted (10) and its scale (12) must be appropriate to the physical facilities available and, especially, to the quality of ventilation (13).

4. *Ventilation—(a) General laboratory ventilation.* This system should: Provide a source of air for breathing and for input to local ventilation devices (199); it should not be relied on for protection from toxic substances released into the laboratory (198); ensure that laboratory air is continually replaced, preventing increase of air concentrations of toxic substances during the working day (194); direct air flow into the laboratory from non-laboratory areas and out to the exterior of the building (194).

(b) *Hoods.* A laboratory hood with 2.5 linear feet of hood space per person should be provided for every 2 workers if they spend most of their time working with chemicals (199); each hood should have a continuous monitoring device to allow convenient confirmation of adequate hood performance before use (200, 209). If this is not possible, work with substances of unknown toxicity should be avoided (13) or other types of local ventilation devices should be provided (199). See pp. 201–206 for a discussion of hood design, construction, and evaluation.

(c) *Other local ventilation devices.* Ventilated storage cabinets, canopy hoods, snorkels, etc. should be provided as needed (199). Each canopy hood and snorkel should have a separate exhaust duct (207).

(d) *Special ventilation areas.* Exhaust air from glove boxes and isolation rooms should be passed through scrubbers or other treatment before release into the regular exhaust system (208). Cold rooms and warm rooms should have provisions for rapid escape and for escape in the event of electrical failure (209).

(e) *Modifications.* Any alteration of the ventilation system should be made only if thorough testing indicates that worker protection from airborne toxic substances will continue to be adequate (12, 193, 204).

(f) *Performance.* Rate: 4–12 room air changes/hour is normally adequate general ventilation if local exhaust systems such as hoods are used as the primary method of control (194).

(g) *Quality.* General air flow should not be turbulent and should be relatively uniform throughout the laboratory, with no high velocity or static areas (194, 195); airflow into and within the hood should not be excessively turbulent (200); hood face velocity should be adequate (typically 60–100 fpm) (200, 204).

(h) *Evaluation.* Quality and quantity of ventilation should be evaluated on installation (202), regularly monitored (at least every 3 months) (6, 12, 14, 195), and reevaluated whenever a change in local ventilation devices is made (12, 195, 207). See pp. 195–198 for methods of evaluation and for calculation of estimated airborne contaminant concentrations.

D. Components of the Chemical Hygiene Plan

1. *Basic Rules and Procedures* (Recommendations for these are given in section E, below)

2. *Chemical Procurement, Distribution, and Storage*

(a) *Procurement.* Before a substance is received, information on proper handling, storage, and disposal should be known to those who will be involved (215, 216). No container should be accepted without an adequate identifying label (216). Preferably, all substances should be received in a central location (216).

(b) *Stockrooms/storerooms.* Toxic substances should be segregated in a well-identified area with local exhaust ventilation (221). Chemicals which are highly toxic (227) or other chemicals whose containers have been opened should be in unbreakable secondary containers (219). Stored chemicals should be examined periodically (at least annually) for replacement, deterioration, and container integrity (218–19).

Stockrooms/storerooms should not be used as preparation or repackaging areas, should be open during normal working hours, and should be controlled by one person (219).

(c) *Distribution.* When chemicals are hand carried, the container should be placed in an outside container or bucket. Freight-only elevators should be used if possible (223).

(d) *Laboratory storage.* Amounts permitted should be as small as practical. Storage on bench tops and in hoods is inadvisable. Exposure to heat or direct sunlight should be avoided. Periodic inventories should be conducted, with unneeded items being discarded or returned to the storeroom/stockroom (225–6, 229).

3. *Environmental Monitoring*

Regular instrumental monitoring of airborne concentrations is not usually justified or practical in laboratories but may be appropriate when testing or redesigning hoods or other ventilation devices (12) or when a highly toxic substance is stored or used regularly (e.g., 3 times/week) (13).

4. *Housekeeping, Maintenance, and Inspections*

(a) *Cleaning.* Floors should be cleaned regularly (24).

(b) *Inspections.* Formal housekeeping and chemical hygiene inspections should be held at least quarterly (6, 21) for units which have frequent personnel changes and semiannually for others; informal inspections should be continual (21).

(c) *Maintenance.* Eye wash fountains should be inspected at intervals of not less than 3 months (6). Respirators for routine use should be inspected periodically by the laboratory supervisor (169). Safety showers should be tested routinely (169). Other safety equipment should be inspected regularly (e.g., every 3–6 months) (6, 24, 171). Procedures to prevent restarting of out-of-service equipment should be established (25).

(d) *Passageways.* Stairways and hallways should not be used as storage areas (24). Access to exits, emergency equipment, and utility controls should never be blocked (24).

5. *Medical Program*

(a) *Compliance with regulations.* Regular medical surveillance should be established to the extent required by regulations (12).

(b) *Routine surveillance.* Anyone whose work involves regular and frequent handling of toxicologically significant quantities of a chemical should consult a qualified physician to determine on an individual basis whether a regular schedule of medical surveillance is desirable (11, 50).

(c) *First aid.* Personnel trained in first aid should be available during working hours and an emergency room with medical personnel should be nearby (173). See pp. 176–178 for description of some emergency first aid procedures.

6. *Protective Apparel and Equipment*

These should include for each laboratory:

(a) Protective apparel compatible with the required degree of protection for substances being handled (158–161);

(b) An easily accessible drench-type safety shower (162, 169);

(c) An eyewash fountain (162);

(d) A fire extinguisher (162–164);

(e) Respiratory protection (164–9), fire alarm and telephone for emergency use (162) should be available nearby; and

(f) Other items designated by the laboratory supervisor (156, 160).

7. *Records*

(a) Accident records should be written and retained (174).

(b) Chemical Hygiene Plan records should document that the facilities and precautions were compatible with current knowledge and regulations (7).

(c) Inventory and usage records for high-risk substances should be kept as specified in sections E3e below.

(d) Medical records should be retained by the institution in accordance with the requirements of state and federal regulations (12).

8. *Signs and Labels*

Prominent signs and labels of the following types should be posted:

(a) Emergency telephone numbers of emergency personnel/facilities, supervisors, and laboratory workers (28);

(b) Identity labels, showing contents of containers (including waste receptacles) and associated hazards (27, 48);

(c) Location signs for safety showers, eyewash stations, other safety and first aid equipment, exits (27) and areas where food and beverage consumption and storage are permitted (24); and

(d) Warnings at areas or equipment where special or unusual hazards exist (27).

9. *Spills and Accidents*

(a) A written emergency plan should be established and communicated to all personnel; it should include procedures for ventilation failure (200), evacuation, medical care, reporting, and drills (172).

(b) There should be an alarm system to alert people in all parts of the facility including isolation areas such as cold rooms (172).

(c) A spill control policy should be developed and should include consideration of prevention, containment, cleanup, and reporting (175).

(d) All accidents or near accidents should be carefully analyzed with the results distributed to all who might benefit (8, 28).

10. Information and Training Program

(a) **Aim:** To assure that all individuals at risk are adequately informed about the work in the laboratory, its risks, and what to do if an accident occurs (5, 15).

(b) **Emergency and Personal Protection Training:** Every laboratory worker should know the location and proper use of available protective apparel and equipment (154, 169).

Some of the full-time personnel of the laboratory should be trained in the proper use of emergency equipment and procedures (6).

Such training as well as first aid instruction should be available to (154) and encouraged for (176) everyone who might need it.

(c) **Receiving and stockroom/storeroom personnel** should know about hazards, handling equipment, protective apparel, and relevant regulations (217).

(d) **Frequency of Training:** The training and education program should be a regular, continuing activity—not simply an annual presentation (15).

(e) **Literature/Consultation:** Literature and consulting advice concerning chemical hygiene should be readily available to laboratory personnel, who should be encouraged to use these information resources (14).

11. Waste Disposal Program

(a) **Aim:** To assure that minimal harm to people, other organisms, and the environment will result from the disposal of waste laboratory chemicals (5).

(b) **Content (14, 232, 233, 240):** The waste disposal program should specify how waste is to be collected, segregated, stored, and transported and include consideration of what materials can be incinerated. Transport from the institution must be in accordance with DOT regulations (244).

(c) **Discarding Chemical Stocks:** Unlabeled containers of chemicals and solutions should undergo prompt disposal; if partially used, they should not be opened (24, 27).

Before a worker's employment in the laboratory ends, chemicals for which that person was responsible should be discarded or returned to storage (226).

(d) **Frequency of Disposal:** Waste should be removed from laboratories to a central waste storage area at least once per week and from the central waste storage area at regular intervals (14).

(e) **Method of Disposal:** Incineration in an environmentally acceptable manner is the most practical disposal method for combustible laboratory waste (14, 238, 241). Indiscriminate disposal by pouring waste chemicals down the drain (14, 231, 242) or adding them to mixed refuse for landfill burial is unacceptable (14).

Hoods should not be used as a means of disposal for volatile chemicals (40, 200).

Disposal by recycling (233, 243) or chemical decontamination (40, 230) should be used when possible.

E. Basic Rules and Procedures for Working with Chemicals

The Chemical Hygiene Plan should require that laboratory workers know and follow its rules and procedures. In addition to the procedures of the sub programs mentioned above, these should include the rules listed below.

1. General Rules

The following should be used for essentially all laboratory work with chemicals:

(a) **Accidents and spills—Eye Contact:** Promptly flush eyes with water for a prolonged period (15 minutes) and seek medical attention (33, 172).

Ingestion: Encourage the victim to drink large amounts of water (178).

Skin Contact: Promptly flush the affected area with water (33, 172, 178) and remove any contaminated clothing (172, 178). If symptoms persist after washing, seek medical attention (33).

Clean-up. Promptly clean up spills, using appropriate protective apparel and equipment and proper disposal (24, 33). See pp. 233–237 for specific clean-up recommendations.

(b) **Avoidance of "routine" exposure:** Develop and encourage safe habits (23); avoid unnecessary exposure to chemicals by any route (23);

Do not smell or taste chemicals (32). Vent apparatus which may discharge toxic chemicals (vacuum pumps, distillation columns, etc.) into local exhaust devices (199).

Inspect gloves (157) and test glove boxes (208) before use.

Do not allow release of toxic substances in cold rooms and warm rooms, since these have contained recirculated atmospheres (209).

(c) **Choice of chemicals:** Use only those chemicals for which the quality of the available ventilation system is appropriate (13).

(d) **Eating, smoking, etc.:** Avoid eating, drinking, smoking, gum chewing, or application of cosmetics in areas where laboratory chemicals are present (22, 24, 32, 40); wash hands before conducting these activities (23, 24).

Avoid storage, handling or consumption of food or beverages in storage areas, refrigerators, glassware or utensils which are also used for laboratory operations (23, 24, 226).

(e) **Equipment and glassware:** Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware (25). Use extra care with Dewar flasks and other evacuated glass apparatus; shield or wrap them to contain chemicals and fragments should implosion occur (25). Use equipment only for its designed purpose (23, 26).

(f) **Exiting:** Wash areas of exposed skin well before leaving the laboratory (23).

(g) **Horseplay:** Avoid practical jokes or other behavior which might confuse, startle or distract another worker (23).

(h) **Mouth suction:** Do not use mouth suction for pipetting or starting a siphon (23, 32).

(i) **Personal apparel:** Confine long hair and loose clothing (23, 158). Wear shoes at all

times in the laboratory but do not wear sandals, perforated shoes, or sneakers (158).

(j) **Personal housekeeping:** Keep the work area clean and uncluttered, with chemicals and equipment being properly labeled and stored; clean up the work area on completion of an operation or at the end of each day (24).

(k) **Personal protection:** Assure that appropriate eye protection (154–156) is worn by all persons, including visitors, where chemicals are stored or handled (22, 23, 33, 154).

Wear appropriate gloves when the potential for contact with toxic materials exists (157); inspect the gloves before each use, wash them before removal, and replace them periodically (157). (A table of resistance to chemicals of common glove materials is given p. 159).

Use appropriate (164–168) respiratory equipment when air contaminant concentrations are not sufficiently restricted by engineering controls (164–5), inspecting the respirator before use (169).

Use any other protective and emergency apparel and equipment as appropriate (22, 157–162).

Avoid use of contact lenses in the laboratory unless necessary; if they are used, inform supervisor so special precautions can be taken (155).

Remove laboratory coats immediately on significant contamination (161).

(l) **Planning:** Seek information and advice about hazards (7), plan appropriate protective procedures, and plan positioning of equipment before beginning any new operation (22, 23).

(m) **Unattended operations:** Leave lights on, place an appropriate sign on the door, and provide for containment of toxic substances in the event of failure of a utility service (such as cooling water) to an unattended operation (27, 128).

(n) **Use of hood:** Use the hood for operations which might result in release of toxic chemical vapors or dust (198–9).

As a rule of thumb, use a hood or other local ventilation device when working with any appreciably volatile substance with a TLV of less than 50 ppm (13).

Confirm adequate hood performance before use; keep hood closed at all times except when adjustments within the hood are being made (200); keep materials stored in hoods to a minimum and do not allow them to block vents or air flow (200).

Leave the hood "on" when it is not in active use if toxic substances are stored in it or if it is uncertain whether adequate general laboratory ventilation will be maintained when it is "off" (200).

(o) **Vigilance:** Be alert to unsafe conditions and see that they are corrected when detected (22).

(p) **Waste disposal:** Assure that the plan for each laboratory operation includes plans and training for waste disposal (230).

Deposit chemical waste in appropriately labeled receptacles and follow all other waste disposal procedures of the Chemical Hygiene Plan (22, 24).

Do not discharge to the sewer concentrated acids or bases (231); highly toxic, malodorous, or lachrymatory substances

(231); or any substances which might interfere with the biological activity of waste water treatment plants, create fire or explosion hazards, cause structural damage or obstruct flow (242).

(q) *Working alone:* Avoid working alone in a building; do not work alone in a laboratory if the procedures being conducted are hazardous (28).

2. Working with Allergens and Embryotoxins

(a) *Allergens* (examples: diazomethane, isocyanates, bichromates): Wear suitable gloves to prevent hand contact with allergens or substances of unknown allergenic activity (35).

(b) *Embryotoxins* (34-5) (examples: organomercurials, lead compounds, formamide): If you are a woman of childbearing age, handle these substances only in a hood whose satisfactory performance has been confirmed, using appropriate protective apparel (especially gloves) to prevent skin contact.

Review each use of these materials with the research supervisor and review continuing uses annually or whenever a procedural change is made.

Store these substances, properly labeled, in an adequately ventilated area in an unbreakable secondary container.

Notify supervisors of all incidents of exposure or spills; consult a qualified physician when appropriate.

3. Work with Chemicals of Moderate Chronic or High Acute Toxicity

Examples: diisopropylfluorophosphate (41), hydrofluoric acid (43), hydrogen cyanide (45).

Supplemental rules to be followed in addition to those mentioned above (Procedure B of "Prudent Practices", pp. 39-41):

(a) *Aim:* To minimize exposure to these toxic substances by any route using all reasonable precautions (39).

(b) *Applicability:* These precautions are appropriate for substances with moderate chronic or high acute toxicity used in significant quantities (39).

(c) *Location:* Use and store these substances only in areas of restricted access with special warning signs (40, 229).

Always use a hood (previously evaluated to confirm adequate performance with a face velocity of at least 60 linear feet per minute) (40) or other containment device for procedures which may result in the generation of aerosols or vapors containing the substance (39); trap released vapors to prevent their discharge with the hood exhaust (40).

(d) *Personal protection:* Always avoid skin contact by use of gloves and long sleeves (and other protective apparel as appropriate) (39). Always wash hands and arms immediately after working with these materials (40).

(e) *Records:* Maintain records of the amounts of these materials on hand, amounts used, and the names of the workers involved (40, 229).

(f) *Prevention of spills and accidents:* Be prepared for accidents and spills (41).

Assure that at least 2 people are present at all times if a compound in use is highly toxic or of unknown toxicity (39).

Store breakable containers of these substances in chemically resistant trays; also work and mount apparatus above such trays or cover work and storage surfaces with removable, absorbent, plastic backed paper (40).

If a major spill occurs outside the hood, evacuate the area; assure that cleanup personnel wear suitable protective apparel and equipment (41).

(g) *Waste:* Thoroughly decontaminate or incinerate contaminated clothing or shoes (41). If possible, chemically decontaminate by chemical conversion (40).

Store contaminated waste in closed, suitably labeled, impervious containers (for liquids, in glass or plastic bottles half-filled with vermiculite) (40).

4. Work with Chemicals of High Chronic Toxicity

(Examples: dimethylmercury and nickel carbonyl (48), benzo-a-pyrene (51), N-nitrosodiethylamine (54), other human carcinogens or substances with high carcinogenic potency in animals (38).)

Further supplemental rules to be followed, in addition to all these mentioned above, for work with substances of known high chronic toxicity (in quantities above a few milligrams to a few grams, depending on the substance) (47). (Procedure A of "Prudent Practices" pp. 47-50).

(a) *Access:* Conduct all transfers and work with these substances in a "controlled area": a restricted access hood, glove box, or portion of a lab, designated for use of highly toxic substances, for which all people with access are aware of the substances being used and necessary precautions (48).

(b) *Approvals:* Prepare a plan for use and disposal of these materials and obtain the approval of the laboratory supervisor (48).

(c) *Non-contamination/Decontamination:* Protect vacuum pumps against contamination by scrubbers or HEPA filters and vent them into the hood (49). Decontaminate vacuum pumps or other contaminated equipment, including glassware, in the hood before removing them from the controlled area (49, 50).

Decontaminate the controlled area before normal work is resumed there (50).

(d) *Exiting:* On leaving a controlled area, remove any protective apparel (placing it in an appropriate, labeled container) and thoroughly wash hands, forearms, face, and neck (49).

(e) *Housekeeping:* Use a wet mop or a vacuum cleaner equipped with a HEPA filter instead of dry sweeping if the toxic substance was a dry powder (50).

(f) *Medical surveillance:* If using toxicologically significant quantities of such a substance on a regular basis (e.g., 3 times per week), consult a qualified physician concerning desirability of regular medical surveillance (50).

(g) *Records:* Keep accurate records of the amounts of these substances stored (229) and used, the dates of use, and names of users (48).

(h) *Signs and labels:* Assure that the controlled area is conspicuously marked with warning and restricted access signs (49) and that all containers of these substances are

appropriately labeled with identity and warning labels (48).

(i) *Spills:* Assure that contingency plans, equipment, and materials to minimize exposures of people and property in case of accident are available (233-4).

(j) *Storage:* Store containers of these chemicals only in a ventilated, limited access (48, 227, 229) area in appropriately labeled, unbreakable, chemically resistant, secondary containers (48, 229).

(k) *Glove boxes:* For a negative pressure glove box, ventilation rate must be at least 2 volume changes/hour and pressure at least 0.5 inches of water (48). For a positive pressure glove box, thoroughly check for leaks before each use (49). In either case, trap the exit gases or filter them through a HEPA filter and then release them into the hood (49).

(l) *Waste:* Use chemical decontamination whenever possible; ensure that containers of contaminated waste (including washings from contaminated flasks) are transferred from the controlled area in a secondary container under the supervision of authorized personnel (49, 50, 233).

5. Animal Work with Chemicals of High Chronic Toxicity

(a) *Access:* For large scale studies, special facilities with restricted access are preferable (56).

(b) *Administration of the toxic substance:* When possible, administer the substance by injection or gavage instead of in the diet. If administration is in the diet, use a caging system under negative pressure or under laminar air flow directed toward HEPA filters (56).

(c) *Aerosol suppression:* Devise procedures which minimize formation and dispersal of contaminated aerosols, including those from food, urine, and feces (e.g., use HEPA filtered vacuum equipment for cleaning, moisten contaminated bedding before removal from the cage, mix diets in closed containers in a hood) (55, 56).

(d) *Personal protection:* When working in the animal room, wear plastic or rubber gloves, fully buttoned laboratory coat or jumpsuit and, if needed because of incomplete suppression of aerosols, other apparel and equipment (shoe and head coverings, respirator) (56).

(e) *Waste disposal:* Dispose of contaminated animal tissues and excreta by incineration if the available incinerator can convert the contaminant to non-toxic products (238); otherwise, package the waste appropriately for burial in an EPA-approved site (239).

F. Safety Recommendations

The above recommendations from "Prudent Practices" do not include those which are directed primarily toward prevention of physical injury rather than toxic exposure. However, failure of precautions against injury will often have the secondary effect of causing toxic exposures. Therefore, we list below page references for recommendations concerning some of the major categories of safety hazards which also have implications for chemical hygiene:

1. Corrosive agents: [35-6]

2. Electrically powered laboratory apparatus: (179-92)
3. Fires, explosions: (26, 57-74, 162-4, 174-5, 219-20, 226-7)
4. Low temperature procedures: (26, 88)
5. Pressurized and vacuum operations (including use of compressed gas cylinders): (27, 75-101)

G. Material Safety Data Sheets

Material safety data sheets are presented in "Prudent Practices" for the chemicals listed below. (Asterisks denote that comprehensive material safety data sheets are provided).

- *Acetyl peroxide (105)
- *Acrolein (106)
- *Acrylonitrile (107)
- Ammonia (anhydrous) (91)
- *Aniline (109)
- *Benzene (110)
- *Benzo[a]pyrene (112)
- *Bis(chloromethyl) ether (113)
- Boron trichloride (91)
- Boron trifluoride (92)
- Bromine (114)
- *Tert-butyl hydroperoxide (148)
- *Carbon disulfide (116)
- Carbon monoxide (92)
- *Carbon tetrachloride (118)
- *Chlorine (119)
- Chlorine trifluoride (94)
- *Chloroform (121)
- Chloromethane (93)
- *Diethyl ether (122)
- Diisopropyl fluorophosphate (41)
- *Dimethylformamide (123)
- *Dimethyl sulfate (125)
- *Dioxane (126)
- *Ethylene dibromide (128)
- *Fluorine (95)
- *Formaldehyde (130)
- *Hydrazine and salts (132)
- Hydrofluoric acid (43)
- Hydrogen bromide (98)
- Hydrogen chloride (98)
- *Hydrogen cyanide (133)
- *Hydrogen sulfide (135)
- Mercury and compounds (52)
- *Methanol (137)
- *Morpholine (138)
- *Nickel carbonyl (99)
- *Nitrobenzene (139)
- Nitrogen dioxide (100)
- N-nitrosodiethylamine (54)
- *Peracetic acid (141)
- *Phenol (142)
- *Phosgene (143)
- *Pyridine (144)
- *Sodium azide (145)
- *Sodium cyanide (147)
- Sulfur dioxide (141)
- *Trichloroethylene (149)
- *Vinyl chloride (150)

Appendix B to § 1910.1450—References (Non-Mandatory)

The following references are provided to assist the employer in the development of a Chemical Hygiene Plan. The materials listed below are offered as non-mandatory guidance. References listed here do not imply

specific endorsement of a book, opinion, technique, policy or a specific solution for a safety or health problem. Other references not listed here may better meet the needs of a specific laboratory. (a) Materials for the development of the Chemical Hygiene Plan:

1. American Chemical Society, Safety in Academic Chemistry Laboratories, 4th edition, 1985.
2. Fawcett, H.H. and W. S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd edition, Wiley-Interscience, New York, 1982.
3. Flury, Patricia A., Environmental Health and Safety in the Hospital Laboratory, Charles C. Thomas Publisher, Springfield IL, 1978.
3. Green, Michael E. and Turk, Amos, Safety in Working with Chemicals, Macmillan Publishing Co., NY, 1978.
5. Kaufman, James A., Laboratory Safety Guidelines, Dow Chemical Co., Box 1713, Midland, MI 48640, 1977.
6. National Institutes of Health, NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Pub. No. 81-2385, GPO, Washington, DC 20402, 1981.
7. National Research Council, Prudent Practices for Disposal of Chemicals from Laboratories, National Academy Press, Washington, DC, 1983.
8. National Research Council, Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Academy Press, Washington, DC, 1981.
9. Renfrew, Malcolm, Ed., Safety in the Chemical Laboratory, Vol. IV, *J. Chem. Ed.*, American Chemical Society, Easlon, PA, 1981.
10. Steere, Norman V., Ed., Safety in the Chemical Laboratory, *J. Chem. Ed.* American Chemical Society, Easlon, PA, 18042, Vol. I, 1967, Vol. II, 1971, Vol. III 1974.
11. Steere, Norman V., Handbook of Laboratory Safety, the Chemical Rubber Company Cleveland, OH, 1971.
12. Young, Jay A., Ed., Improving Safety in the Chemical Laboratory, John Wiley & Sons, Inc. New York, 1987.

(b) Hazardous Substances Information:

1. American Conference of Governmental Industrial Hygienists, Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes, P.O. Box 1937 Cincinnati, OH 45201 (latest edition).
2. Annual Report on Carcinogens, National Toxicology Program U.S. Department of Health and Human Services, Public Health Service, U.S. Government Printing Office, Washington, DC, (latest edition).
3. Best Company, Best Safety Directory, Vols. I and II, Oldwick, N.J., 1981.
4. Bretherick, L., Handbook of Reactive Chemical Hazards, 2nd edition, Butterworths, London, 1979.
5. Bretherick, L., Hazards in the Chemical Laboratory, 3rd edition, Royal Society of Chemistry, London, 1986.
6. Code of Federal Regulations, 29 CFR part 1910 subpart Z. U.S. Govt. Printing Office, Washington, DC 20402 (latest edition).

7. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, World Health Organization Publications Center, 49 Sheridan Avenue, Albany, New York 12210 (latest editions).

8. NIOSH/OSHA Pocket Guide to Chemical Hazards, NIOSH Pub. No. 85-114, U.S. Government Printing Office, Washington, DC, 1985 (or latest edition).

9. Occupational Health Guidelines, NIOSH/OSHA NIOSH Pub. No. 81-123 U.S. Government Printing Office, Washington, DC, 1981.

10. Patty, F.A., Industrial Hygiene and Toxicology, John Wiley & Sons, Inc., New York, NY (Five Volumes).

11. Registry of Toxic Effects of Chemical Substances, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Revised Annually, for sale from Superintendent of Documents U.S. Govt. Printing Office, Washington, DC 20402.

12. The Merck Index: An Encyclopedia of Chemicals and Drugs, Merck and Company Inc. Rahway, N.J., 1976 (or latest edition).

13. Sax, N.I. Dangerous Properties of Industrial Materials, 5th edition, Van Nostrand Reinhold, NY., 1979.

14. Sittig, Marshall, Handbook of Toxic and Hazardous Chemicals, Noyes Publications, Park Ridge, NJ, 1981.

(c) Information on Ventilation:

1. American Conference of Governmental Industrial Hygienists Industrial Ventilation, 16th edition Lansing, MI, 1980.

2. American National Standards Institute, Inc. American National Standards Fundamentals Governing the Design and Operation of Local Exhaust Systems ANSI Z 9.2-1979 American National Standards Institute, N.Y. 1979.

3. Imad, A.P. and Watson, C.L. Ventilation Index: An Easy Way to Decide about Hazardous Liquids, Professional Safety pp 15-18, April 1980.

4. National Fire Protection Association, Fire Protection for Laboratories Using Chemicals NFPA-45, 1982.

Safety Standard for Laboratories in Health Related Institutions, NFPA, 58c, 1980.

Fire Protection Guide on Hazardous Materials, 7th edition, 1978.

National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.

5. Scientific Apparatus Makers Association (SAMA), Standard for Laboratory Fume Hoods, SAMA LF7-1980, 1101 16th Street, NW., Washington, DC 20036.

(d) Information on Availability of Referenced Material:

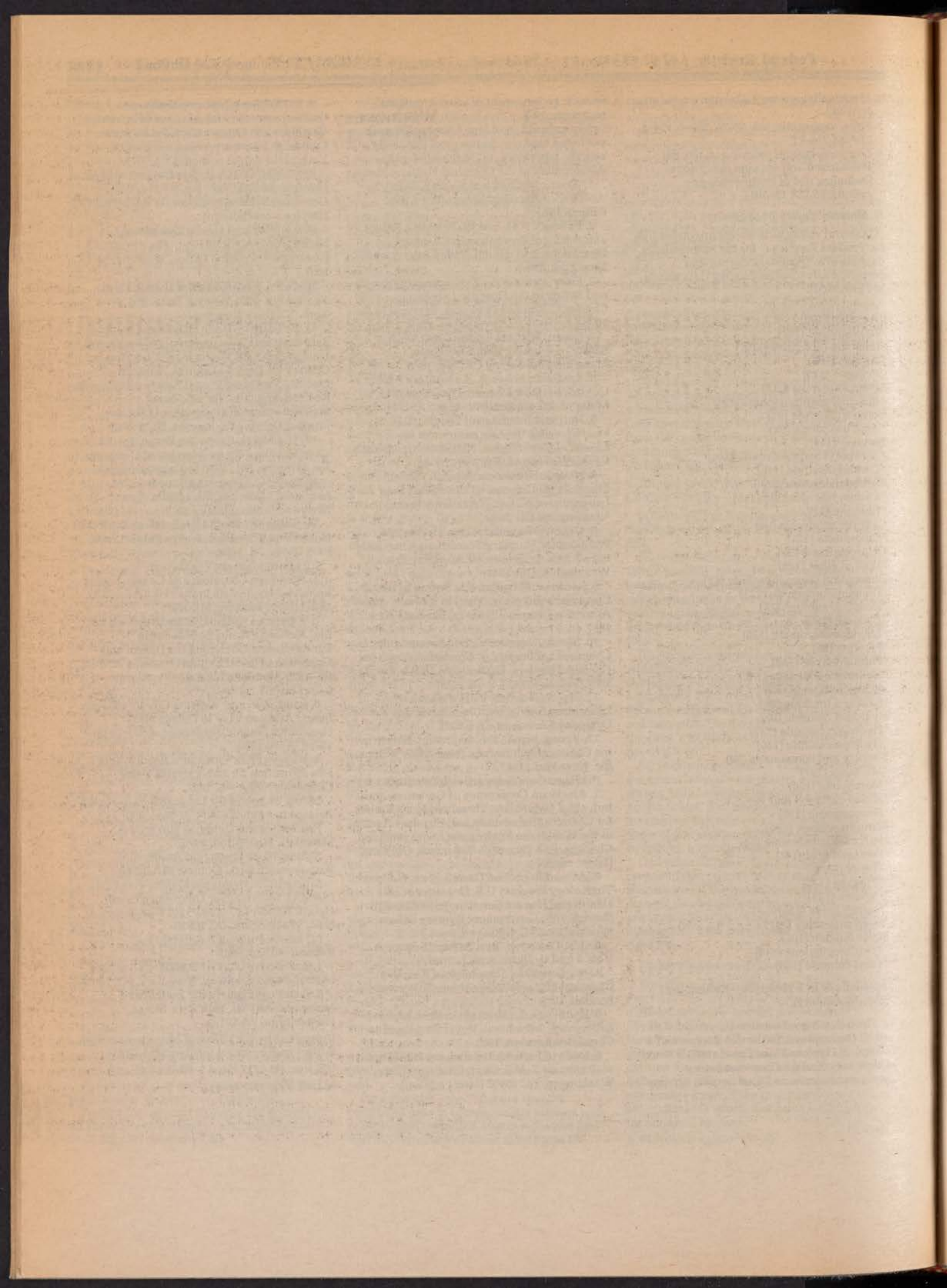
1. American National Standards Institute (ANSI), 1430 Broadway, New York, NY 10018.

2. American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103.

(Approved by the Office of Management and Budget under control number 1218-0131)

[FR Doc. 90-1717 Filed 1-30-90; 8:45 am]

BILLING CODE 4510-26-M



Best Start Program

Wednesday
January 31, 1990

Part III

Department of Education

**New Awards for Fiscal Year 1990; Notice
Inviting Applications**

DEPARTMENT OF EDUCATION

[CFDA No. 84.220]

Notice Inviting Applications for New Awards for Fiscal Year 1990 Under the Centers for International Business Education Program

Note to Applicants: This notice is a complete application package. Together with the statute authorizing the program and applicable regulations governing the program, including the Education Department General Administrative Regulations (EDGAR), the notice contains information, application forms, and instructions needed to apply for a grant under this competition.

Purpose of Program: The purpose of the Centers for International Business Education Program is to provide grants to eligible institutions of higher education, or combinations of these institutions, to pay the Federal share of the cost of planning, establishing and operating Centers for International Business Education that will—

(1) Be national resources for the teaching of improved business techniques, strategies, and methodologies that emphasize the international context in which business is transacted;

(2) Provide instruction in critical foreign languages and international fields needed to provide an understanding of the cultures and customs of United States trading partners;

(3) Provide research and training in the international aspects of trade, commerce, and other fields of study;

(4) Provide training to students enrolled in the institution, or combinations of institutions, in which a center is located; and

(5) Serve as regional resources to businesses proximately located by offering programs and providing research designed to meet the international training needs of these businesses.

Deadline for Transmittal of

Applications: April 16, 1990.

Available Funds: \$2,700,000.

Estimated Range of Awards: \$250,000–\$350,000.

Estimated Average Size of Awards: \$300,000.

Estimated Number of Awards: 7–9.

Note: The Department is not bound by any estimates in this notice.

Project Period: 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR part 74 (Administration of Grants to Institutions of Higher

Education, Hospitals, and Nonprofit Organizations), part 75 (Direct Grant Programs); part 77 (Definitions that Apply to Department Regulations); and part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)); (b) The Centers for International Business Education Program statute, codified under title VI, part B, section 612, of the Higher Education Act of 1965, as amended by section 6261 of the Omnibus Trade and Competitiveness Act of 1988, Public Law 100-418 (20 U.S.C. 1130-1).

Eligibility: To be eligible for assistance under this program, an applicant must be an institution of higher education, or a combination of these institutions, that establishes a Center Advisory Council prior to the date that Federal assistance is received. The Center Advisory Council must conduct extensive planning prior to the establishment of a Center for International Business Education concerning the scope of the Center's activities and the design of its programs.

The Center Advisory Council must include—

(1) One representative of an administrative department or office of the institution of higher education (or a combination of these institutions);

(2) One faculty representative of the business or management school or department of the institution (or a combination of these institutions);

(3) One faculty representative of the international studies or foreign language school or department of the institution (or a combination of these institutions);

(4) One faculty representative of another professional school or department of the institution (or a combination of these institutions), as appropriate;

(5) One or more representatives of local or regional businesses or firms;

(6) One representative appointed by the Governor of the State in which the institution (or a combination of these institutions) is located whose normal responsibilities include official oversight or involvement in State-sponsored trade-related activities or programs; and

(7) Such other individuals as the institution of higher education (or a combination of these institutions) deems appropriate.

Programmatic Requirements:

Programs and activities to be conducted by Centers for International Business Education assisted under this program must include—

(1) Interdisciplinary programs which incorporate foreign language and international studies training into

business, finance, management, communications systems, and other professional curricula;

(2) Interdisciplinary programs which provide business, finance, management, communications systems, and other professional training for foreign language and international studies faculty and advanced degree candidates;

(3) Evening or summer programs, including, but not limited to, intensive language programs, available to members of the business community and other professionals which are designed to develop or enhance their international skills, awareness, and expertise;

(4) Collaborative programs, activities, or research involving other institutions of higher education, local educational agencies, professional associations, businesses, firms or combinations thereof, to promote the development of international skills, awareness, and expertise among current and prospective members of the business community and other professionals;

(5) Research designed to strengthen and improve the international aspects of business and professional education and to promote integrated curricula; and

(6) Research designed to promote the international competitiveness of American businesses and firms, including those not currently active in international trade.

Other Allowable Activities: Programs and activities to be conducted by Centers for International Business Education assisted under this program may also include—

(1) The establishment of overseas internship programs for students and faculty designed to provide training and experience in international business activities, except that no Federal funds provided under this program may be used to pay wages or stipends to any participant who is engaged in compensated employment as part of an internship program; and

(2) Other eligible activities consistent with the purposes and intent of the legislation.

Funding Requirements: The applicant's share of the cost of planning, establishing and operating centers under this section may not be less than—

(1) 10 per centum for the first year in which Federal funds are furnished;

(2) 30 per centum for the second year; and

(3) 50 per centum for the third year and for each year thereafter.

The non-Federal share of the cost of planning, establishing, and operating centers under this program may be

provided either in cash or by in-kind assistance.

Other Requirements: The statute requires applicants to provide—

(1) An assurance that the Center Advisory Council will meet not less than once each year after the establishment of the Center to assess and advise on the programs and activities conducted by the Center;

(2) A description of the extensive planning that the Center Advisory Council and the institution of higher education, or a combination of these institutions, have conducted or will conduct prior to the establishment of the Center for International Business Education, concerning the scope of the center's activities and the design of its programs;

(3) An assurance of ongoing collaboration in the establishment and operation of the Center by faculty of the business, management, foreign language, international studies other professional schools or departments, as appropriate;

(4) An assurance that the education and training programs of the Center will be open to students concentrating in each of these respective areas, as appropriate; and

(5) An assurance that the institution of higher education, or combination of these institutions, will use the assistance provided under this section to supplement and not to supplant activities conducted by the institution or institutions of higher education.

Allowable Costs: Grant funds may be used to pay the Federal share of the cost of planning, establishing or operating a Center, including the cost of—

(1) Faculty and staff travel in foreign areas, regions, or countries;

(2) Teaching and research materials;

(3) Curriculum planning and development;

(4) Bringing visiting scholars and faculty to the center to teach or to conduct research;

(5) Training and improvement of the staff, for the purpose of, and subject to such conditions as the Secretary finds necessary, for carrying out the objectives of this program; and

(6) Other costs consistent with planning, establishing or operating a Center. The applicant may complete a copy of Standard Form 424A, printed in the application package, for each year for which funding is requested, and may use section F of Standard Form 424A to provide a detailed breakout of all proposed costs for each 12 month period for which funding is requested. Under 34 CFR 75.562, the Secretary accepts an indirect cost rate of 8 percent of the total direct cost of the project.

Selection Criteria: (a)(1) The Secretary uses the following selection criteria to evaluate applications for new grants under the Centers for International Business Education Program.

(2) The maximum score for all of these criteria is 100 points.

(3) The maximum score for each criterion is indicated in parentheses with the criterion.

(b) *The criteria—*(1) *Meeting the purposes of the authorizing statute.* (30 points) The Secretary reviews each application to determine how well the project will meet the purpose of title VI, part B, section 612, of the Higher Education Act of 1965, as amended by section 6261 of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 (20 U.S.C. 1130-1), including consideration of—

(i) The objectives of the project; and

(ii) How the objectives of the project further the purposes of the authorizing statute.

(2) *Extent of need for the project.* (20 points) The Secretary reviews each application to determine the extent to which the project meets specific needs recognized in the statute that authorizes the program, including consideration of—

(i) The needs addressed by the project;

(ii) How the applicant identified those needs;

(iii) How those needs will be met by the project; and

(iv) The benefits to be gained by meeting those needs.

(3) *Plan of operation.* (25 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(i) The quality of the design of the project;

(ii) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(iii) How well the objectives of the project relate to the purpose of the program, as stated in the Purpose of Program section of this notice;

(iv) The quality of the applicant's plan to use its resources and personnel to achieve each objective; and

(v) How the applicant will ensure that project participants who are otherwise eligible to participate are selected without regard to race, color, national origin, gender, age, or handicapping condition; and

(vi) For grants under a program that requires the applicant to provide an opportunity for participation of students enrolled in private schools, the quality

of the applicant's plan to provide that opportunity.

(4) *Quality of key personnel.* (7 points)

(i) The Secretary reviews each application to determine the quality of key personnel the applicant plans to use on the project, including—

(A) The qualifications of the project director (if one is to be used);

(B) The qualifications of each of the other key personnel to be used in the project;

(C) The time that each person referred to in paragraph (b)(4)(i) (A) and (B) of this section will commit to the project; and

(D) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping condition.

(ii) To determine personnel qualifications under paragraphs (b)(4)(i) (A) and (B) of the section, the Secretary considers—

(A) Experience and training in fields related to the objectives of the project; and

(B) Any other qualifications that pertain to the quality of the project.

(5) *Budget and cost effectiveness.* (10 points) The Secretary reviews each application to determine the extent to which—

(i) The budget is adequate to support the project; and

(ii) Costs are reasonable in relation to the objectives of the project.

(6) *Evaluation plan.* (5 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(i) Are appropriate to the project; and

(ii) To the extent possible, are objective and produce data that are quantifiable.

(Cross-reference: See 34 CFR 75.590 Evaluation by the grantee)

(7) *Adequacy of resources.* (3 points) The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(Approved under OMB Control No. 1840-0616)

Instructions for Transmittal of Applications

No grant may be awarded unless a complete form has been received.

(a) If an applicant wants a new grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education Application Control Center, Attention: (CFDA # 84.220) Washington, DC 20202-4725.

or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. (Washington, DC time) on the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # 84.200) room 3633, 7th & D Streets SW., ROB-3, Washington, DC.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) The Application Control Center will mail a Grant Application Receipt Acknowledgment to each applicant. If an applicant fails to receive the notification of application receipt within 15 days from the date of mailing the application, the applicant should call the U.S. Department of Education Control Center at (202) 732-2495.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in Item 10 of this application form for Federal assistance (Standard Form 424) the CFDA number—and letter, if any—of the competition under which the application is being submitted.

Application Instructions and Forms

The appendix to this application is divided into three parts. These parts are organized in the same manner that the submitted application should be organized. The parts are as follows:

Part I: Application for Federal Assistance (Standard Form 424 Rev. 4-88) and instructions.

Part II: Budget Information—Non-Construction Programs (Standard Form 424A) and instructions.

Part III: Application Narrative. Assurances—Non-Construction Programs (Standard Form 424B) and instructions.

Assurances—Centers for International Business Education Program.

Certification regarding Debarment, Suspension, and other

Responsibility Matters: Primary Covered Transactions (ED Form GCS-008) and instructions.

Certification regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form GCS-009) and instructions.

(Note: ED Form GCS-009 is intended for the use of primary participants and should not be transmitted to the Department.)

One or both of the following, as appropriate: Certification Regarding Drug-Free Workplace Requirements:

Grantees Other than Individuals (ED80-0004).

Certification Regarding Drug-Free Workplace Requirements:

Grantees Who Are Individuals (ED-0005).

Certification Regarding Lobbying for Grants and Cooperative Agreements (ED 80-0008).

(Note: This form is required if requesting, making, or entering into a grant or cooperative agreement for more than \$100,000)

Disclosure of Lobbying Activities (Standard Form LLL) (if applicable) and instructions; and Disclosure of Lobbying Activities Continuation Sheet (Standard Form LLL-A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certification. However, the application form, the assurances, and the certification must each have an original signature. No grant may be awarded unless a completed application form has been received.

For Further Information Contact: For specific information concerning the program, contact: Susanna C. Easton, Center for International Education, Office of Postsecondary Education, Department of Education, Room 3053, ROB-3, 400 Maryland Avenue SW., Washington, DC 20202. Telephone: (202) 732-3302.

Program Authority: (20 U.S.C. 1130-1).

Dated: January 8, 1990.

Leonard Haynes,
Assistant Secretary for Postsecondary Education.

BILLING CODE 4000-01-M

OMB Approval No. 0348-004.

APPLICATION FOR FEDERAL ASSISTANCE		2. DATE SUBMITTED	Applicant Identifier
1. TYPE OF SUBMISSION: Application <input type="checkbox"/> Construction <input checked="" type="checkbox"/> Non-Construction Preapplication <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction	3. DATE RECEIVED BY STATE	State Application Identifier	
4. DATE RECEIVED BY FEDERAL AGENCY		Federal Identifier	
5. APPLICANT INFORMATION			
Legal Name:		Organizational Unit:	
Address (give city, county, state, and zip code):		Name and telephone number of the person to be contacted on matters involving this application (give area code)	
6. EMPLOYER IDENTIFICATION NUMBER (EIN): <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>		7. TYPE OF APPLICANT: (enter appropriate letter in box)	
8. TYPE OF APPLICATION: <input checked="" type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es): <input type="checkbox"/> <input type="checkbox"/> A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Other (specify):		A. State H. Independent School Dist. B. County I. State Controlled Institution of Higher Learning C. Municipal J. Private University D. Township K. Indian Tribe E. Interstate L. Individual F. Intermunicipal M. Profit Organization G. Special District N. Other (Specify):	
9. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:		9. NAME OF FEDERAL AGENCY:	
8 4 2 2 0 TITLE: CENTERS FOR INTERNATIONAL BUSINESS EDUCATION		U.S. DEPARTMENT OF EDUCATION	
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):		11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:	
13. PROPOSED PROJECT: Start Date Ending Date		14. CONGRESSIONAL DISTRICTS OF: a. Applicant b. Project	
15. ESTIMATED FUNDING:		16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?	
a. Federal	\$.00	a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE _____	
b. Applicant	\$.00	b. NO. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372 <input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
c. State	\$.00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT? <input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No	
d. Local	\$.00		
e. Other	\$.00		
f. Program Income	\$.00		
g. TOTAL	\$.00		
18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED			
a. Typed Name of Authorized Representative		b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed	

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-10.

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry: | Item: | Entry: |
|-------|--|-------|--|
| 1. | Self-explanatory. | 12. | List only the largest political entities affected (e.g., State, counties, cities). |
| 2. | Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable). | 13. | Self-explanatory. |
| 3. | State use only (if applicable). | 14. | List the applicant's Congressional District and any District(s) affected by the program or project. |
| 4. | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank. | 15. | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate <u>only</u> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5. | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application. | 16. | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. |
| 6. | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service. | 17. | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes. |
| 7. | Enter the appropriate letter in the space provided. | 18. | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.) |
| 8. | Check appropriate box and enter appropriate letter(s) in the space(s) provided:
— "New" means a new assistance award.
— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. | | |
| 9. | Name of Federal agency from which assistance is being requested with this application. | | |
| 10. | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested. | | |
| 11. | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project. | | |

OMB Approval No. 0348-0044

BUDGET INFORMATION — Non-Construction Programs

SECTION A — BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget	
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)
1.		\$	\$	\$	\$
2.					
3.					
4.					
5. TOTALS		\$	\$	\$	\$

SECTION B — BUDGET CATEGORIES

Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	\$	\$	\$	\$	\$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	\$	\$	\$	\$	\$
7. Program Income	\$	\$	\$	\$	\$

Authorized for Local Reproduction

Standard Form 424A (4-88)
Prescribed by OMB Circular A-102

SECTION C - NON-FEDERAL RESOURCES					
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS	
8.	\$	\$	\$	\$	
9.					
10.					
11.					
12. TOTALS (sum of lines 8 and 11)	\$	\$	\$	\$	
SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	\$	\$	\$	\$	\$
13. Federal		\$	\$	\$	\$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	\$	\$	\$	\$	\$
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT					
(a) Grant Program	FUTURE FUNDING PERIODS (Years)				(e) Fourth
	(b) First	(c) Second	(d) Third	(e) Fourth	
16.	\$	\$	\$	\$	\$
17.					
18.					
19.					
20. TOTALS (sum of lines 16-19)	\$	\$	\$	\$	\$
SECTION F - OTHER BUDGET INFORMATION (Attach additional sheets if Necessary)					
21. Direct Charges:	22. Indirect Charges:				
23. Remarks					

INSTRUCTIONS FOR THE SF-424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary
Lines 1-4, Columns (a) and (b)-

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in Column (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g.)

For *new applications*, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

Lines 1-4, Columns (c) through (g.) (continued)

For *continuing grant program applications*, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instruction provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For *supplemental grants and changes* to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 — Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the title of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a-i — Show the totals of Lines 6a to 6h in each column.

Line 6j — Show the amount of indirect cost.

Line 6k — Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

INSTRUCTIONS FOR THE SF-424A (continued)

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 - Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16 - 18 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

Instructions for Part III—Application Narrative

Before preparing the Application Narrative, an applicant should read carefully all the information included in this notice. The Secretary recommends that you carefully consider the sections of this notice pertaining to the Purpose of the Program and the Programmatic Requirements as you address the selection criteria the Secretary uses to evaluate applications.

The narrative should—

1. Begin with an Abstract; that is, a summary of the proposed project.
2. Include the following information in order to establish eligibility under this program:

(a) The date the Center Advisory Council was or will be established.

Note: The Advisory Council shall be established prior to the date that Federal assistance is received.

(b) A list of the members of the Advisory Council and a description of their academic or other affiliations.

(c) A description of the extensive planning which was or will be conducted by the Advisory Council prior to the establishment of the Center for International Business Education, concerning the scope of the center's activities and the design of its programs.

3. Describe the proposed Center for International Business Education in light of each of the selection criteria in the order in which the criteria are listed in this notice and describe the activities proposed to be carried out in each year of the 3-year funding cycle under the "Plan of Operation" section of the application.

4. Include any other pertinent information that might assist the Secretary in reviewing the application. Please limit the Application Narrative to 55 double-spaced, typed pages (on one side only). Please do not use reduced size type script. Supporting materials may be appended.

Estimated Public Reporting Burden

Under terms of the Paperwork Reduction Act of 1980, as amended, and

the regulations implementing that Act, the Department of Education invites comment on the public reporting burden in this collection of information. Public reporting burden for this collection of information is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, DC 20202-4651; and to the Office of Management and Budget, Paperwork Reduction Project 1840-0616, Washington, DC 20503.

(Information collection approved under OMB control number 1840-0616 Expiration date 2/92)

BILLING CODE 4000-01-M

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE	
APPLICANT ORGANIZATION		DATE SUBMITTED

Assurances

Instructions: Applicants are required to provide the following assurances: This assurance form must be signed by authorized representatives of the legal applicants.

Assurances—Centers for International Business Education

The applicant hereby assures and certifies that:

1. In addition to conducting the extensive planning activities required under the eligibility section of the

statute, the center advisory council shall meet not less than once a year after the establishment of the center to assess and advise on the programs and activities conducted by the center;

2. There shall be ongoing collaboration in the establishment and operation of the center by faculty of the business, management, foreign language, international studies and other professional schools or departments, as appropriate;

3. The education and training programs of the center will be open to

students concentrating in each of these respective areas, as appropriate; and

4. The applicant will use the assistance provided under this program to supplement and not to supplant activities already being conducted by the applicant.

Name And Title of Authorized Representative

Signature

Date

BILLING CODE 4000-01-M

**Certification Regarding
Debarment, Suspension, and Other Responsibility Matters
Primary Covered Transactions**

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 *Federal Register* (pages 19160-19211). Copies of the regulations may be obtained by contacting the U.S. Department of Education, Grants and Contracts Service, 400 Maryland Avenue, S.W. (Room 3633 GSA Regional Office Building No. 3), Washington, D.C. 20202-4725, telephone (202) 732-2505.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

- (1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
- (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
 - (b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
 - (c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and
 - (d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.
- (2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name

PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature

Date

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.
2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.
4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.
6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.
7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

**Certification Regarding
Debarment, Suspension, Ineligibility and Voluntary Exclusion
Lower Tier Covered Transactions**

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211). Copies of the regulations may be obtained by contacting the person to which this proposal is submitted.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

- (1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
- (2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name

PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature

Date

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification Regarding Drug-Free Workplace Requirements Grantees Other Than Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 *Federal Register*, require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 34 CFR Part 85, Sections 85.615 and 85.620).

The grantee certifies that it will provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing a drug-free awareness program to inform employees about--
 - (1) The dangers of drug abuse in the workplace;
 - (2) The grantee's policy of maintaining a drug-free workplace;
 - (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
 - (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will--
 - (1) Abide by the terms of the statement; and
 - (2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;
- (e) Notifying the agency within ten days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction;
- (f) Taking one of the following actions, within 30 days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted--
 - (1) Taking appropriate personnel action against such an employee, up to and including termination; or
 - (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
- (g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Organization Name

PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature

Date

Certification Regarding Drug-Free Workplace Requirements

Grantees Who Are Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 *Federal Register*, require certification by grantees, prior to award, that their conduct of grant activity will be drug-free. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 34 CFR Part 85, Sections 85.615 and 85.620).

The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant.

Organization Name (As Appropriate)

PR/Award Number or Project Name

Printed Name

Signature

Date

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

Approved by OMB
0346-0046

1. Type of Federal Action: <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. Report Type: <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known: Congressional District, if known: _____		5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime: Congressional District, if known: _____
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, if applicable: _____	
8. Federal Action Number, if known:	9. Award Amount, if known: \$ _____	
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI):		b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI):
(attach Continuation Sheet(s) SF-LLL-A, if necessary)		
11. Amount of Payment (check all that apply): \$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned	13. Type of Payment (check all that apply): <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee <input type="checkbox"/> c. commission <input type="checkbox"/> d. contingent fee <input type="checkbox"/> e. deferred <input type="checkbox"/> f. other; specify: _____	
12. Form of Payment (check all that apply): <input type="checkbox"/> a. cash <input type="checkbox"/> b. in-kind; specify: nature _____ value _____		
14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11: (attach Continuation Sheet(s) SF-LLL-A, if necessary)		
15. Continuation Sheet(s) SF-LLL-A attached: <input type="checkbox"/> Yes <input type="checkbox"/> No		
16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.		Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____
Federal Use Only:		Authorized for Local Reproduction Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

**DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET**Approved by OMB
0348-0046

Reporting Entity: _____

Page _____ of _____

**Certification Regarding Lobbying For
Grants and Cooperative Agreements**

Submission of this certification is required by Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into a grant or cooperative agreement over \$100,000.

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement.
- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, 'Disclosure Form to Report Lobbying,' in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact on which the Department of Education relied when it made or entered into this grant or cooperative agreement. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Organization Name

PR/Award (or Application) Number
or Project Name

Name and Title of Authorized Representative

Signature

Date

ED 80-0008

12/89

Fastest Great Product

Wednesday
January 31, 1990

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 347 and 348

Skin Protection and External Analgesic Products for Fever Blister and Cold Sore Treatment Products; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 347**

[Docket No. 78N-021F]

RIN 0905-AA06

Skin Protectant Drug Products for Over-the-Counter Human Use; Fever Blister and Cold Sore Treatment Drug Products

AGENCY: Food and Drug Administration.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) skin protectant drug products. The proposed rulemaking would establish conditions under which OTC skin protectant drug products for the treatment of fever blisters and cold sores are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement on OTC drug products for the treatment of fever blisters by the Advisory Review Panel on OTC Miscellaneous External Drug Products, public comments on an advance notice of proposed rulemaking that was based on that statement, and public comments on the notice of proposed rulemaking for OTC skin protectant drug products. (See the *Federal Register* of February 15, 1983; 48 FR 6820.) The agency's proposals concerning the external use of other OTC drug products for treating fever blisters and cold sores are being published elsewhere in this issue of the *Federal Register*. Orally administered drug products for OTC use for the treatment of fever blisters are being addressed in a separate OTC drug rulemaking. The agency's proposals concerning those products were published in the *Federal Register* of June 17, 1985 (50 FR 25156). These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by May 31, 1990. The agency is allowing a period of 120 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of two rulemakings regarding OTC drug products for fever blisters and cold sores and (2) this document contains the

first published evaluation of several submissions of data on OTC drug products for the treatment of these conditions that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by January 31, 1991. Comments on the new data by April 1, 1991. Written comments on the agency's economic impact determination by May 31, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 7, 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC external analgesic drug products (47 FR 39412) and skin protectant drug products (47 FR 39436). The notices were published to allow for consideration of statements on OTC drug products for the treatment of fever blisters. The statements were prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for this condition. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the *Federal Register* of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC skin protectant drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

One trade association and one drug manufacturer submitted comments concerning the use of skin protectant drug products for the treatment of fever blisters and cold sores. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided a general statement on OTC drug products for the treatment of fever blisters, but did not review individual ingredients and did not develop labeling for drug products for this indication. Several submissions to the Panel were for drug products used to treat the symptoms (i.e., itching, minor irritations) of fever blisters and cold sores by the mechanism of providing a physical or mechanical barrier to protect the exposed skin surfaces from harmful or annoying stimuli. However, a number of skin protectant drug products labeled for the treatment of fever blisters and cold sores were not submitted to the Miscellaneous External Panel.

Therefore, the agency is expanding the scope of this segment of the skin protectant rulemaking to include all OTC skin protectant drug products labeled for any of these uses.

In this document, the agency is addressing comments concerning drug products for the treatment of fever blisters and cold sores when the mechanism of action for these uses involves the ingredient's ability to provide a mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli. In the external analgesic rulemaking (published elsewhere in this issue of the *Federal Register*), the agency is addressing claims for the treatment of symptoms of fever blisters and cold sores when the mechanism of action for these claims involves the ingredient's causing depression or stimulation of cutaneous sensory receptors.

In the *Federal Register* of February 15, 1983 (48 FR 6820), the agency published a tentative final monograph (proposed rule) for OTC skin protectant drug products, but it did not address products labeled for the treatment of cold sores and fever blisters. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations.

Interested persons were invited to submit comments by April 18, 1983, new data by February 15, 1984, and comments on new data by April 16, 1984. In response to that notice, one drug manufacturer submitted a comment concerning the use of skin protectant ingredients for the treatment of fever blisters and cold sores. The agency is also addressing that comment in this notice of proposed rulemaking. A copy

of the comment received is on public display in the Dockets Management Branch (address above).

In this notice of proposed rulemaking, FDA responds to public comment and further discusses its position on OTC skin protectant drug products for the treatment of fever blisters and cold sores. Final agency action on this matter will occur with the publication of a future date of a final rule relating to OTC skin protectant drug products for these conditions.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with

the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register on November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

1. One comment requested that the following claims be added to the skin protectant monograph: "for the temporary relief of discomfort of cold sores, fever blisters, sun blisters and herpes or herpes labialis lesions" and "for relief from the discomfort of cold sores (herpes), sun and fever blisters." The comment contended that "the initial exposure (or longer exposure, i.e., 'overexposure') to stronger sunlight is the precipitating factor or cause of a 'fever blister/cold sore.'" The comment stated that, under such conditions, the consumer usually refers to herpes lip lesions as "sun blisters" (which they do not confuse with the same-named "sun-blisters" that may follow a sunburn). The comment added that its marketing experience indicates that sun exposure, as described above, is the major cause of herpes labialis. The comment supported use of the terms "herpes" and "herpes labialis" in OTC labeling on the Miscellaneous External Panel's statement at 47 FR 39442 which reads,

Fever blisters" and "cold sores" are common names for herpes simplex, an acute infectious disease caused by the * * * virus *Herpes simplex*, type 1 * * *. The usual site of the lesion is at the junction of the mucous membrane and skin of the lips or nose. Hence, the term *herpes labialis* is frequently used.

The comment concluded that the terms "sun blisters," "herpes," and "herpes labialis" are acceptable OTC labeling when reference is clearly understood to be to the lips as it is with cold sores and fever blisters.

A second comment requested that the claim "For the temporary relief of

discomfort of cold sores and fever blisters," be added to the skin protectant monograph for Category I ingredients in proposed § 347.10 that are used to relieve symptoms of dryness and for Category I combinations in proposed § 347.20. The comment contended that part of the Panel's discussion of the treatment of fever blisters at 47 FR 39443 that "drying agents such as * * * skin protectant agents may be useful," supports its request.

In the amendment to the external analgesic tentative final monograph, published elsewhere in this issue of the Federal Register, the agency addresses the fever blister drug product claims "for the temporary relief of discomfort of cold sores, fever blisters, sun blisters, and herpes or herpes labialis lesions," "for relief from the discomfort of cold sores (herpes), sun and fever blisters," and "for the temporary relief of discomfort of cold sores and fever blisters." Claims for the relief of discomfort (pain or ache) are considered in that monograph proceeding rather than here in the skin protectant monograph, which covers claims for the relief of dryness associated with cold sores and fever blisters. (See also comment 2 below.)

2. One comment requested that the following indication be added to the tentative final monograph for OTC skin protectant drug products for the individual active ingredients listed in proposed § 347.10: "Softens crusts (scabs) associated with cold sores and fever blisters." Another comment requested that this indication be included only for the skin protectant active ingredients in proposed § 347.10 that relieve symptoms of dryness, i.e., allantoin, cocoa butter, dimethicone, glycerin, petrolatum, shark liver oil, and white petrolatum. Both comments requested that this indication be included for the combinations in proposed § 347.20. In support of their requests, the comments cited the Miscellaneous External Panel's statement on OTC drug products for the treatment of fever blisters at 47 FR 39443, which reads, "Although most viral infections cannot be cured by OTC drugs, fever blisters should not be neglected * * * ointments (protectants) can soften crusts * * *. Drying agents such as alcohols, astringents, or skin protectant agents may be useful * * *." A third comment stated that the indication "Relieves dry, chapped lips, cold sores, and fever blisters" would be acceptable for the skin protectant active ingredients which relieve symptoms of dryness.

In the advance notice of proposed rulemaking on OTC skin protectant drug products, the Topical Analgesic Panel defined the terms absorbent, demulcent, and emollient (43 FR 34628 at 34630), and discussed them in relation to the above-listed ingredients' effect in softening the skin. The Panel concluded that allantoin absorbs moisture (43 FR 34633), dimethicone is a demulcent (43 FR 34636), glycerin is an absorbent, demulcent, and emollient (43 FR 34637), and petrolatum, white petrolatum, and shark liver oil are emollients (43 FR 34639). The Miscellaneous External Panel stated at 47 FR 39443 that protectants can soften crusts.

The agency concludes that "softening crusts (scabs)" results from the absorbent, demulcent, or emollient properties exhibited by skin protectant ingredients that treat or relieve dryness. The softening or moisturizing effect of these ingredients keeps the cold sores or fever blisters moist and prevents drying and fissuring, which may render those lesions more susceptible to secondary bacterial infection, may delay healing, and usually increases discomfort (Ref. 1). This effect would result from any of these skin protectant ingredients applied individually or in the combinations proposed in § 347.20(b), as requested by the comments. Based on these two panels' discussions, the agency is proposing in this skin protectant tentative final monograph for fever blister and cold sore drug products that any product containing any of the above active ingredients individually or in combination as set forth in § 347.20(b) of the tentative final monograph may make the following claim: "Softens crusts (scabs) associated with cold sores and fever blisters."

The agency does not believe that the claim "Relieves dry, chapped lips, cold sores, and fever blisters" sufficiently states what symptom is being relieved by the product. However, as discussed above, the protectant ingredients do relieve dryness by "softening." Accordingly, the agency believes that a more appropriate indication would be: "Relieves dryness and softens cold sores and fever blisters." This claim is being proposed as an additional claim for these products in § 347.50(b)(2)(ii) in this tentative final monograph on OTC skin protectant drug products. Claims related to chapped lips appear in § 347.50(b)(2) of the tentative final monograph for OTC skin protectant drug products published on February 15, 1983; 48 FR 6820. That section is being redesignated as § 347.50(b)(2)(i) in this document.

Reference

(1) Baker, A. B., and D. K. Helling, "Oral Health Products" in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association and The National Professional Society of Pharmacists, Washington, p. 492, 1986.

3. Referring to the rulemaking for topical antimicrobial drug products, one comment requested that the administrative records on alcohol drug products and on first aid antibiotic drug products be reopened to include claims for fever blisters and cold sores. In support of its request, the comment cited the Miscellaneous External Panel's September 7, 1982, statements on OTC drug products for the treatment of fever blisters at 47 FR 39418 to 39420 and at 47 FR 39441 to 39443, i.e.,

Although most viral infections cannot be cured by OTC drugs, fever blisters should not be neglected. Local anesthetics can relieve pain, antibiotics can control secondary bacterial infections when they occur, and ointments (protectants) can soften crusts * * *. Drying agents such as alcohols, astringents, or skin protectant agents may be useful * * *.

The comment contended that, based on the Panel's views, proposed § 333.98(b) should be amended to add the claim for alcohol, "To dry fever blisters and to protect against secondary bacterial infection" and that § 333.150(b) should be amended to include the following claims for first aid antibiotics: "Protectant for small (minor) cuts, abrasions, burns and fever blisters," and "Protects against secondary bacterial infection." The comment did not submit any data in support of claims relating to fever blisters and cold sores.

The Panel's statements were general in nature and unsubstantiated by data for any specific ingredients. Therefore, claims relating to fever blisters as requested by the comment were not included in the antimicrobial rulemakings.

The agency invites the submission of data relating to specific alcohol and/or topical first aid antibiotic ingredients (or combinations) for the above or similar claims for fever blisters and cold sores. Alcohol and first aid antibiotics are being handled in separate proceedings within the antimicrobial rulemaking. Alcohol drug products will be covered in a tentative final monograph for OTC first aid antiseptic drug products to be published in a future issue of the *Federal Register*. That rulemaking will include indications relating to first aid to help reduce the risk of infection in minor cuts, scrapes, and burns. Data on the use of alcohol drug products to dry fever blisters and to protect against infection

should be submitted to that rulemaking. A final monograph for the first aid antibiotic segment of the antimicrobial rulemaking was published on December 11, 1987 (52 FR 47312). Therefore any supporting data requesting the inclusion of a fever blister claim in that monograph must be submitted in the form of a citizen petition to amend the final monograph. (See 21 CFR 10.30 and 330.10(a)(12).)

4. One comment suggested that the combination policy proposed in § 347.20 be amended to allow a combination of a skin protectant and a sunscreen for protection and prevention of sun and fever blisters. The comment stated that the usefulness of a sunscreen agent in preventing these blisters and lesions is evident from the Miscellaneous External Panel's own reasoning. The comment cited the Panel's statement at 47 FR 39443 that "such events as fever, chilling, sunburn, windburn, menstruation, upset stomach or gastrointestinal disturbance, emotional stress or excitement may reduce the immune state sufficiently for the virus to become activated and again cause an infection, designated recurrent herpes." The comment also cited the report on Orally Administered Drug Products for the Treatment of Fever Blisters for OTC Human Use by the Advisory Review Panel on OTC Miscellaneous Internal Drug Products in which the Panel stated that exposure to sunlight could cause recurrent herpes (January 5, 1982; 47 FR 504).

The comment further contended that persons prone to "sun blisters" should avoid undue exposure to sunlight in the ultraviolet light range, which is thought to be the precipitating factor; namely, 290 nanometers up to and through the visible light wavelengths. The comment stated that this excess exposure can be reduced with the use of effective topical sunscreens.

The comment argued that products containing combinations of Category I skin protectants and sunscreen ingredients should thus be recognized as safe and effective for the prevention and relief of discomfort of fever blisters, sun blisters, and cold sores (herpes). The comment added that this combination would meet the Topical Analgesic Panel's general combination policy at 43 FR 34632 and the agency's policy on fixed combination prescription drugs at 21 CFR 300.50. The comment claimed that it has marketing experience to support the claim that effective protection from the sun can help prevent sun-induced herpes or lip "sun blisters."

The comment requested the following indications for the skin protectant-

sunscreen combination product:

"Protects and helps prevent sun and fever blisters caused by overexposure to the sun," and "Filters (or screens or blocks [if applicable]) out the sun's rays to help prevent (lip) sun blisters." The comment contended that these claims convey the action of the drug product to the consumer and should be acceptable OTC labeling.

A second comment also requested that the skin protectant monograph provide for combination skin protectant-sunscreen products for the treatment of fever blisters with the labeling claim, "Helps protect lips and blisters of the lips from the adverse effects of overexposure to the sun." As support, the comment cited the Topical Analgesic Panel's statement at 43 FR 38217, which states "The Panel also concludes that sunscreen active ingredients may be combined with other active ingredients, e.g., skin protectants, provided that the ingredients are generally recognized as safe and effective, i.e., Category I active ingredients."

The agency acknowledges the statements made by the Miscellaneous Internal Panel and by the Miscellaneous External Panel concerning the effect of sunlight on causing recurrent herpes. However, the Panel's statements were not substantiated by supportive data showing that the use of a sunscreen will either treat or prevent fever blisters or cold sores. The purpose of the sunscreen ingredient in the combination appears to be prevention, while the skin protectant ingredient is intended to provide protection to the affected area. The agency's combination policy requires that each ingredient in a combination product make a contribution to the product's claimed effect. The comments primarily presented arguments, rather than data, in support of the use of a sunscreen ingredient to prevent the occurrence of fever blisters.

Accordingly, data from clinical studies are needed to demonstrate that a combination product containing a skin protectant ingredient and a sunscreen ingredient is needed for concurrent administration and to support the role of the sunscreen ingredient. Specifically, data are needed to support the use of a combination product when the consumer has fever blisters and is using the skin protectant ingredient for protection of the fever blister. The role of the sunscreen component of the combination needs to be established during the time of this combined use. Therefore, the agency is classifying the combination of a skin protectant and a sunscreen ingredient in Category III, and invites the submission of data in support

of the comment's contention that sunlight causes "sun blisters," and that a sunscreen will prevent their recurrence. Data are also needed to demonstrate that a target population exists which can benefit from concurrent use of the two types of ingredients in the same product. The claims requested by the comment will be considered when adequate supporting data for the combination product have been submitted.

5. One comment suggested that § 347.20 of the tentative final monograph for OTC skin protectant drug products be amended to include combinations of astringent active ingredients in proposed § 347.12 with skin protectant active ingredients in § 347.10 or combinations of skin protectant active ingredients in § 347.20. The comment stated that the Panel was aware that OTC ingredients are used on lesions amenable to treatment by skin protectants and astringents, that the pharmacological action of these ingredients is well known, and that astringents are used in both cosmetics and drug products.

In the tentative final monograph for OTC skin protectant astringent drug products (April 3, 1989; 54 FR 13490), the agency classified a combination of a skin protectant and an astringent in Category III. In comment 3 of that document, the agency invited public comment and the submission of data supportive of such a combination. Because the above comment did not submit any data, the combination remains in Category III.

II. The Agency's Evaluation of the Submissions

The Miscellaneous External Panel discussed only in general the use of OTC drug products for the treatment of fever blisters and cold sores. The Panel recommended that the agency consider in appropriate rulemakings ingredients and labeling claims submitted for treating fever blisters, cold sores, and their related symptoms (47 FR 39436 at 39442).

In this document, the agency discusses the use of OTC skin protectant drug products for the treatment of fever blisters and cold sores. The agency has evaluated three submissions (Refs. 1, 2, and 3) that were not reviewed by the Panel. Two of the submissions (Refs. 1 and 2) include drug products that have since been reformulated. Another manufacturer has requested that its submissions (Refs. 4 through 9) be withdrawn from further consideration for all claims (Ref. 10). These submissions concerned drug products containing stabilized aloe vera gel for topical use for numerous

indications, including the treatment of fever blisters.

References

- (1) OTC Volume 160012.
- (2) OTC Volume 160013.
- (3) OTC Volume 160048.
- (4) OTC Volume 160252A.
- (5) OTC Volume 160252B.
- (6) OTC Volume 160273.
- (7) OTC Volume 160274.
- (8) OTC Volume 160422.
- (9) OTC Volume 160423.
- (10) Letter from A.J. Davis, Aloe Vera of America, Inc., to W.E. Gilbertson, FDA, dated May 20, 1988, in OTC Volume O6FBSTFM.

6. One comment contended that tannic acid should be placed in Category I as an astringent in fever blister products. Referring to the reopening of the administrative record for the rulemaking for OTC external analgesic drug products on September 7, 1982 (47 FR 39412), the comment cited the Miscellaneous External Panel's discussion of tannic acid as an astringent active ingredient in fever blister products in which the Panel concludes that "tannic acid in low concentrations applied to a small area such as a fever blister would be safe, but the data submitted on the use of this ingredient in treating fever blisters are insufficient to establish effectiveness," (47 FR 39419). The comment also cited the Panel's statement that:

Astringents are locally applied protein precipitants which have such a low cell penetrability that the action is essentially limited to the cell surface and the interstitial spaces * * *. The astringent action is accompanied by contraction and wrinkling of the tissue and by blanching. The cement substance of the capillary endothelium is hardened * * * thus the affected area becomes drier (47 FR 39426).

The comment believed that such action would permit a fever blister to atrophy and that this action would indicate the effectiveness of tannic acid applied to small areas of the lips to treat fever blisters. The comment, therefore, requested that tannic acid be placed in Category I as an astringent active ingredient in the tentative final monograph on OTC skin protectant drug products.

The Panel received submissions (Refs. 1 and 2) from one manufacturer for two combination products containing tannic acid and labeled as providing relief for cold sores and fever blisters. One product (in liquid form) listed tannic acid 2.86 percent, benzalkonium chloride (50 percent U.S.P.) 0.04 percent, and benzocaine 0.95 percent as the active ingredients (Ref. 1), and one product (in stick form) listed tannic acid 3 percent,

allantoin 0.2 percent, benzocaine 1 percent, menthol 0.1 percent, camphor 0.1 percent, benzalkonium chloride 0.04 percent, and a sunscreen agent 0.75 percent (Ref. 2). More recent labeling provided by the manufacturer identifies three combination products in a roll-on, stick, and liquid concentrate form for use in the relief of cold sores and fever blisters (Ref. 3). The active ingredients listed in these products are tannic acid 6 percent, benzocaine 5 to 10 percent, and benzalkonium chloride 0.12 percent. The stick form also contains several additional active ingredients.

The submissions included articles from the scientific and medical literature and some data on the safety and effectiveness of allantoin, benzalkonium chloride, and benzocaine. They also included an oral toxicity and primary skin irritation report on a combination product containing approximately 3 percent tannic acid. The oral toxicity study involved the oral administration of the product to 25 male albino rats. The LD₅₀ was determined to be 24.03 milliliters per kilogram body weight. Upon autopsy of animals that survived for 14 days after treatment, no abnormalities of thoracic or abdominal organs were observed. The primary skin irritation study consisted of clipping the hair from the abdomen of six male albino rabbits, designating two areas of the abdomen for application, abrading one site and leaving the other site unabraded, applying the drug product to the areas, covering the areas with pieces of cotton gauze and a polyethylene film, and taping. The report stated that the primary irritation score was 0.16 (using the general technique of scoring described by Draize) and concluded that this indicated that the sample is not a primary skin irritant. The report concluded that the product was neither orally toxic nor a primary skin irritant (Ref. 1). The submission (Ref. 1) also contained testimonial letters pertaining to the use of the products for the treatment of fever blisters and cold sores.

Tannic acid has been reviewed in a number of OTC drug rulemakings. The Topical Analgesic Panel reviewed tannic acid in the advance notice of proposed rulemaking for OTC skin protectant drug products (August 4, 1978; 43 FR 34628) and concluded that the documented hepatotoxicity resulting from the use of tannic acid makes it unsuitable for use as an OTC skin protectant (43 FR 34644). In the tentative final monograph for OTC skin protectant drug products (February 15, 1983; 48 FR 6820), the agency concurred with the Topical Analgesic Panel's Category II

classification of tannic acid based on the data cited by the Panel that showed that tannic acid in varying concentrations is absorbed when applied topically to large areas of severe burns (48 FR 6825).

In the advance notice of proposed rulemaking for OTC drug products for the relief of ingrown toenail, published in the *Federal Register* of October 17, 1980 (45 FR 69128 at 69131 to 69132), the Miscellaneous External Panel acknowledged the potential hepatotoxic effect of tannic acid but classified it as Category I for safety in concentrations up to 25 percent based on the conclusion that tannic acid is applied to small areas of intact skin and has very little action on intact skin. In the tentative final monograph for OTC ingrown toenail relief drug products published in the *Federal Register* of September 3, 1982 (47 FR 39120), the agency concurred with the Panel's Category I classification of tannic acid for safety (47 FR 39121). The agency's conclusions were based on the comments of the Antimicrobial II Panel contained in the advance notice of proposed rulemaking for OTC topical antifungal drug products, published in the *Federal Register* of March 23, 1982 (47 FR 12480), in which the Panel concluded that topically applied tannic acid is likely to interact with surface proteins so extensively that even when used on the fissured areas of athlete's foot, percutaneous absorption of this ingredient is unlikely (47 FR 12521). The agency stated that in the case of a small puncture of the skin that may be caused by an ingrown toenail, a similar reaction will result, and absorption is unlikely to occur (47 FR 39121).

In a reopening of the administrative records for OTC external analgesic (47 FR 39412) and skin protectant drug products (47 FR 39436), the Miscellaneous External Panel concluded that tannic acid in low concentrations applied to a small area such as a fever blister would be safe (47 FR 39419 and 47 FR 39443). However, the Panel did not specify what concentration would be considered safe and effective.

The use of tannic acid in an ingrown toenail relief drug product is primarily for application to small areas of intact skin surrounding an ingrown toenail. As the Miscellaneous External Panel noted (47 FR 39436 at 39442 to 39443), the usual site of fever blister lesions is at the junction of the mucous membrane and the skin on the lips or nose, and the primary herpetic infection in the nonimmune person manifests itself by vesicles (blisters) on the mucous membranes in the mouth. The agency is concerned about the degree of

absorption through the mucous membrane and through oral ingestion that may occur when tannic acid is applied in proximity to the mouth. The agency is also concerned that the necessity for frequent applications of medication to those areas, accompanied by eating and drinking, may result in toxicity through oral ingestion.

The agency also notes that the safety studies in the submission were for drug products containing approximately 3 percent tannic acid and the current products containing approximately 3 percent tannic acid and the current products contain 6 percent tannic acid (Ref. 3). No safety data on the combination products containing 6 percent tannic acid were provided. For these reasons, the agency is classifying tannic acid for topical use in treating the symptoms of fever blisters and cold sores in Category III for safety.

The submissions (Refs. 1 and 2) did not provide any data to support the effectiveness of the combination products in relieving the discomfort of fever blisters nor did the manufacturer provide data to demonstrate the effectiveness of tannic acid alone in relieving the symptoms of fever blisters and cold sores. Further, the testimonial letters included in one submission (Ref. 1) are not adequate to establish effectiveness because isolated case reports, random experience reports, and reports lacking details which permit scientific evaluation are not considered in establishing effectiveness. (See 21 CFR 330.10(a)(4)(ii).) In addition, the agency notes that a number of the letters questioned both the safety and effectiveness of the products.

The agency acknowledges that the Miscellaneous External Panel did recognize that an astringent may be useful in the treatment of fever blisters, stating that " * * * it may be a rational treatment in shortening the healing time of fever blisters (47 FR 39436 at 39443). However, in the tentative final monograph for OTC fever blister drug products that amends the tentative final monograph for OTC external analgesic products, published elsewhere in this issue of the *Federal Register*, the agency raises concerns regarding the safety and effectiveness of astringents in treating the symptoms of fever blisters and cold sores. The agency referred to a discussion on cold sore treatment in the "Handbook of Nonprescription Drugs" (Ref. 4) that states that products which are highly astringent are best avoided, and that a cold sore should be kept moist to prevent drying and fissuring; this "cracking" of the lesions may render them more susceptible to

secondary bacterial infection, may delay healing, and usually increases discomfort. The agency also expressed concerns regarding the effect of astringents on fractionating the herpes simplex virus and possibly producing resistant strains. Therefore, the agency believes that data from clinical studies are needed to establish both the safety and the effectiveness of astringents for use in treating the symptoms of fever blisters and cold sores.

Based on the above, at this time, the agency is classifying tannic acid for topical use to relieve the symptoms of cold sores and fever blisters in Category III for both safety and effectiveness. Any combination product containing tannic acid as an active ingredient would also be Category III.

References

- (1) OTC Volume 160012.
- (2) OTC Volume 160013.
- (3) Comment No. AMD-002, Docket No. 78N-0021, Dockets Management Branch.
- (4) Baker, A. B., and D. K. Helling, "Oral Health Products" in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association and The National Professional Society of Pharmacists, Washington, p. 492, 1986.

7. One manufacturer submitted animal safety data (Ref. 1) to the Miscellaneous External Panel for a lip balm product labeled "for relief of dry, chapped lips, cold sores, sun and fever blisters" and "for relief of and to help heal and prevent fever blisters, cold sores, sunburned, raw, dry chapped lips." These data consisted of controlled studies using the finished drug product for rabbit eye irritation, rabbit dermal irritation, and guinea pig LD₅₀. The manufacturer contended that these data show that the product is neither an ocular nor a primary dermal irritant, and its acute oral LD₅₀ is greater than 8 grams per kilogram body weight for rats. The manufacturer did not submit any human safety or effectiveness data, but provided marketing experience information and testimonial letters about the product.

The product's labeling listed the following ingredients: sesame oil, paraffin, octyldodecanol, white petrolatum, beeswax, pyridoxine hydrochloride, spermaceti, amyl dimethyl *p*-aminobenzoate, allantoin, titanium dioxide, propyl *p*-benzoate, BHA, flavoring, and fragrance. The active ingredient(s) were not designated on the label; however, pyridoxine hydrochloride was specified as the only active ingredient in a protocol to compare the product with a placebo for the treatment of *herpes simplex* (Ref. 2). The manufacturer recently provided

information that pyridoxine hydrochloride is no longer considered an active ingredient but is an inactive ingredient used to provide a slightly acidic buffered pH (Refs. 3 and 4).

Product information in the 1989 Physicians' Desk Reference for Nonprescription Drugs (Ref. 5) indicates that this product contains pyridoxine hydrochloride, allantoin, and the sunscreens octyl-*p*-(dimethylamino)-benzoate (padimate O) and titanium dioxide. This information conveys the impression that pyridoxine hydrochloride is an active ingredient in the product. As a result of that perception, the agency is evaluating pyridoxine hydrochloride as an active ingredient in this rulemaking. Although animal safety data for the product were submitted, none of these data are attributable to pyridoxine hydrochloride as an individual ingredient. No data were submitted to support the effectiveness of pyridoxine hydrochloride as an individual active ingredient to treat fever blisters. Therefore, the agency is classifying it in Category II for that use. Notwithstanding the manufacturer's recent claim that it is an inactive ingredient (Refs. 3 and 4), the agency is not aware of any information supportive of the use of pyridoxine hydrochloride as an acidic buffering agent. The agency will seek to clarify such a use prior to publication of a final monograph for skin protectant fever blister treatment drug products.

The manufacturer's most recent information (Ref. 3) indicated that the product contains 4 active ingredients—2 skin protectants, allantoin and petrolatum, and 2 sunscreens, padimate O and titanium dioxide, and has claims of "emollient relief," "healing properties," and "sun protection" in its insert (Ref. 6). Although allantoin 0.5 to 2 percent and petrolatum and 30 to 100 percent are classified in Category I in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832), at this time there is insufficient evidence of the use of either of these ingredients for treatment of fever blisters. Accordingly, the agency is classifying these skin protectant ingredients in Category III for use on cold sores and fever blisters.

The other 2 active ingredients padimate O and titanium dioxide are being considered in the rulemaking for OTC sunscreen drug products (43 FR 38206). The use of a sunscreen to treat fever blisters and cold sores will be addressed in that rulemaking in a future issue of the Federal Register.

References

- (1) OTC Volume 160048.
- (2) OTC Volume 160048, Exhibit V. C. 1.
- (3) Letter from R. Zahn, Campbell Laboratories, Inc., to W. E. Gilbertson, FDA, dated November 1, 1989, in OTC Volume 06FBSTFM.
- (4) Memorandum of telephone conversations, November 1 and 2, 1989, between R. Zahn, Campbell Laboratories, Inc., and M. T. Benson, FDA, in OTC Volume 06FBSTFM.
- (5) "Physicians' Desk Reference For Nonprescription Drugs," 10th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 536-537, 1989.
- (6) Labeling submitted by R. Zahn, Campbell Laboratories, Inc., to W. E. Gilbertson, FDA, dated October 25, 1989, in OTC Volume 06FBSTFM.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statements

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.* The discussion below only applies to skin protectant drug products used for the treatment of fever blisters and cold sores. External analgesic drug products used for the treatment of symptoms of fever blisters and cold sores are discussed in the external analgesic rulemaking published elsewhere in this issue of the Federal Register.

Although the Miscellaneous External Panel mentioned the use of skin protectant ingredients for the treatment of fever blisters, it did not review or classify the individual ingredients. Most of the ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statement on OTC drug products for the treatment of fever blisters (47 FR 39436 at 39442). The Panel noted at 47 FR 39442 that many of these ingredients labeled with claims as skin protectant drug products for treatment of fever blisters have been previously addressed by other OTC advisory review panels. The agency is aware that many of these products were reviewed by the Topical Analgesic Panel.

The agency has further considered the Topical Analgesic Panel's recommendations on OTC skin protectant drug products (43 FR 34628), the tentative final monograph on OTC skin protectant drug products (48 FR 6820), and the additional data and information on tannic acid (see comment 6 above), pyridoxine hydrochloride (see comment 7 above), and zinc sulfate. Although data on zinc sulfate were submitted only to the external analgesic drug products rulemaking, the agency believes it is

appropriate to consider zinc sulfate for classification in the skin protectant drug products rulemaking because of its chemical relationship to other zinc salts already included in the rulemaking, its astringent action as discussed elsewhere in this issue of the *Federal Register*, and its claimed drying and crusting effect which provides protection and more closely resembles the action of skin protectant ingredients.

Based upon the above discussion, the agency is adding three entries to the "Summary of Ingredient Categories" table for skin protectant active ingredients that appeared in the tentative final monograph for OTC skin protectant drug products (48 FR 6820). These additions involve ingredients used for the treatment of fever blisters and cold sores, i.e., pyridoxine hydrochloride, tannic acid, and zinc sulfate. The ingredient tannic acid is currently being classified in Category III for fever blister/cold sore use. Tannic acid for all other skin protectant uses remains in Category II. An updated table appears below for the convenience of the reader.

SUMMARY OF INGREDIENT CATEGORIES

Skin protectant active ingredients	Category
Allantoin ¹	I
Aluminum hydroxide gel.....	I
Bismuth subnitrate.....	II
Boric acid.....	II
Calamine.....	I
Cocoa butter.....	I
Dimethicone.....	I
Glycerin.....	I
Kaolin.....	I
Live yeast cell derivative ²	III
Petrolatum.....	I
Pyridoxine hydrochloride (for fever blister/cold sore use).....	II
Shark liver oil.....	I
Sodium bicarbonate.....	I
(a) for the temporary protection and relief of itching due to poison ivy/oak/sumac, and insect bites.....	I
(b) for drying, oozing, and weeping.....	III
(c) as an insect bite neutralizer.....	II
Sulfur.....	II
Tannic acid (for fever blister/cold sore use).....	III
Tannic acid (for other skin protectant uses).....	II
Topical starch ³	III
Trolamine ⁴	III
White petrolatum.....	I
Zinc acetate ¹	I
Zinc carbonate.....	I
Zinc oxide.....	I
Zinc sulfate (for fever blister/cold sore use).....	III

¹ Also classified by the Topical Analgesic Panel and the agency as a Category III wound healing agent.

² Classified only as a wound healing agent.

³ Although "corn starch" was the designated name by the Miscellaneous External Panel for this ingredient, "Topical starch" is the official title used in the United States Pharmacopeia, XXI Revision—The National Formulary XVI, "United States Pharmacopoeial Convention, Inc., Rockville, MD, p. 984, 1985.

⁴ Identified by the Miscellaneous External Panel as triethanolamine.

In its statement, the Miscellaneous External Panel also listed a number of other ingredients that it said should be considered in other appropriate rulemakings for their use in treating fever blisters and cold sores, and their related symptoms (47 FR 39436 at 39442). The Panel recommended that the ingredients allantoin, glycerin, petrolatum, tannic acid, and white petrolatum for use on fever blisters be referred to the rulemaking on skin protectant ingredients and that other ingredients be referred to rulemakings which FDA considers appropriate. The agency notes that many of the ingredients listed by the Panel were intended as inactive ingredients, and they need not be reviewed as skin protectants for use on fever blisters. They are: ammonium carbonate, aromatic oily solution, beeswax, BHA, candelilla wax, carnauba wax, castor oil, cetyl alcohol, lanolin, lanolin alcohol, mineral oil, octyldodecanol, ozokerite, paraffin, peppermint oil, petrolatum, propyl *p*-benzoate, sorbitan sesquiolate, soya sterol, spermaceti, titanium dioxide, wheat germ glycerides, and white petrolatum. One ingredient was listed under three names and was submitted as active and inactive, i.e., Escalol 506, amyl dimethyl *p*-aminobenzoate, and amyl para-dimethylaminobenzoate. That ingredient is also known as padimate-A, a Category I sunscreen ingredient, which together with homosalate has been deferred to the sunscreen rulemaking. Alcohol, calcium silicate, and talcum powder were not submitted to the Panel, although alcohol is being deferred to the rulemaking on OTC first-aid antiseptic drug products for use on cuts and wounds. Benzalkonium chloride is also being deferred to that rulemaking. The following active ingredients were deferred to the rulemaking on OTC external analgesic drug products: ammonia, benzocaine, bismuth sodium tartrate, camphor, menthol, pectin, and phenol. The following ingredients were deferred to the oral cavity drug products rulemaking: anhydrous glycerol and carbamide peroxide. Pyridoxine hydrochloride has been considered in this rulemaking.

2. *Testing of Category II and Category III conditions.* The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any skin protectant ingredient or conditions included in the review for the

treatment of fever blisters and cold sores, by following the procedures outlined in the agency's policy statement published in the *Federal Register* of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the substance of the Miscellaneous External Panel's statements, including the Panel's description of what "fever blisters" and "cold sores" are. This Panel did not recommend a specific monograph for skin protectant drug products for use in the treatment of fever blisters and cold sores. However, the Topical Analgesic Panel did recommend a monograph for skin protectant drug products (43 FR 34628), and the agency adopted this recommended monograph with some revisions in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832). The agency is amending that proposed monograph to include conditions for the treatment of fever blisters and cold sores based on its evaluations of the data and its responses to the comments described above, and the other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency is adding a definition for "fever blister, cold sore" in proposed § 347.3(f), as follows: "A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus *herpes simplex*, type 1."

2. In addition to the statement of identity in § 347.50(a)(1), "skin protectant," the agency is proposing to add new paragraph (a)(4) as an appropriate alternative statement of identity for skin protectant drug products used for the treatment of cold sores or fever blisters to read as follows: (4) *For products containing any ingredient in § 347.10 (a), (d), (e), (f), (h), (i), or (j).* "Fever blister/cold sore treatment." The agency considers this proposed statement of identity to be descriptive and informative to consumers.

3. The agency is redesignating proposed § 347.50(b)(2) as § 347.50(b)(2)(i) and is adding new paragraph (b)(2)(ii) to read as follows:

(ii) "Relieves dryness and softens cold sores and fever blisters," which may be followed by the optional statement "Softens crusts (scabs) associated with cold sores and fever blisters." (See comment 2 above.)

4. The agency is classifying pyridoxine hydrochloride in Category II and zinc sulfate in Category III as skin protectants for the treatment of fever blisters and cold sores. (See comment 7 and part III, paragraph A.1. above.)

5. The agency is classifying the combination of a skin protectant and a sunscreen in Category III for the protection and prevention of sun and fever blisters. Data are needed to demonstrate the role of sunlight in causing "sun blisters" and that a sunscreen will prevent their recurrence. In addition, data are needed to demonstrate the existence of a target population which can benefit from the concurrent use of the two types of ingredients in the same product. (See comment 4 above.)

6. The agency is classifying the combination of a skin protectant and astringent for the treatment of fever blisters and cold sores in Category III. (See comment 5 above.)

7. The agency provided for combination products containing skin protectant(s) and external analgesic(s) in § 348.20 of the external analgesic tentative final monograph (48 FR 5868) and in the amended external analgesic tentative final monograph for the treatment of fever blisters and cold sores being published elsewhere in this issue of the **Federal Register**. Accordingly, the combination of a skin protectant(s) and an external analgesic(s) is not being included in this tentative final monograph but an appropriate cross-reference to part 348 is being included.

8. The agency proposes that the warnings and directions currently included in proposed § 347.50 (c) and (d) be applicable for products labeled for the treatment of fever blisters and cold sores.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for

OTC skin protectant drug products for the treatment of fever blisters and cold sores, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC skin protectant drug products for the treatment of fever blisters and cold sores is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC skin protectant drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by May 31, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before May 31, 1990, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before May 31, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between

9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before January 31, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category L. Written comments on the new data may be submitted on or before April 1, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC skin protectant drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on April 1, 1991. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs, Fever blister drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in part 347 (as proposed in the **Federal Register** of February 15, 1983; 48 FR 6820) as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 347 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 347.3 is amended by adding and reserving paragraph (e) and by adding new paragraph (f) to read as follows:

§ 347.3 Definitions.

(e) [Reserved]

(f) *Fever blister, cold sore.* A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus *herpes simplex*, type 1.

3. Section 347.20 is amended by adding new paragraph (d) to read as follows:

§ 347.20 Permitted combinations of active ingredients.

(d) *Skin protectant and external analgesic combinations.* See § 348.20 of this chapter.

4. Section 347.50 is amended by adding new paragraph (a)(4), by redesignating paragraph (b)(2) as paragraph (b)(2)(i), and by adding new paragraph (b)(2)(ii) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

(a) * * *

(4) For products containing any ingredient in § 347.10(a), (d), (e), (f), (h), (i), or (j), "Fever blister/cold sore treatment."

(b) * * *

(2) * * *

(ii) "Relieves dryness and softens cold sores and fever blisters," which may be followed by the optional statement, "Softens crusts (scabs) associated with cold sores and fever blisters."

Dated: December 25, 1989.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-2164 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 348

[Docket No. 78N-301F]

RIN 0905-AA06

External Analgesic Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Fever Blister and Cold Sore Treatment Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC)

external analgesic drug products. The proposed rulemaking would establish conditions under which OTC external analgesic drug products for the treatment of fever blisters and cold sores are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement of OTC drug products for the treatment of fever blisters by the Advisory Review Panel on OTC Miscellaneous External Drug Products, and public comments on an advance notice of proposed rulemaking that was based on that statement. The agency's proposals concerning the external use of other OTC drug products for treating fever blisters and cold sores are being published elsewhere in this issue of the Federal Register. Orally administered drug products for OTC use for the treatment of fever blisters are being addressed in a separate OTC drug rulemaking. The agency's proposals concerning those products were published in the Federal Register of June 17, 1985 (50 FR 25156). These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by May 31, 1990. The agency is allowing a period of 120 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of two rulemakings regarding OTC drug products for fever blisters and cold sores and (2) this document contains the first published evaluation of several submissions of data on OTC drug products for the treatment of these conditions that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by January 21, 1991. Comments on the new data by April 1, 1991. Written comments on the agency's economic impact determination by May 31, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7, 1982,

FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC external analgesic drug products (47 FR 39412) and skin protectant drug products (47 FR 39436). The notices were published to allow for consideration of statements on OTC drug products for the treatment of fever blisters. The statements were prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for this condition. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the Federal Register of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC external analgesic drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

One trade association, one physician, and five drug manufacturers submitted comments concerning the use of external analgesic drug products for the treatment of fever blisters and cold sores. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided a general statement of OTC drug products for the treatment of fever blisters, but did not review individual ingredients and did not develop labeling for drug products for this indication. Several submissions to the Panel were for drug products used to treat the symptoms (i.e., itching, minor irritations) of fever blisters and cold sores by the mechanism of depressing or stimulating cutaneous sensory receptors. However, a number of external analgesic drug products labeled for the treatment of fever blisters and cold sores were not submitted to the Miscellaneous External Panel. Therefore, the agency is expanding the scope of this segment of the external analgesic rulemaking to include all OTC external analgesic drug products labeled for any of these uses.

In this document, the agency is addressing comments concerning drug products for the treatment of fever blisters and cold sores when the mechanism of action for these uses involves the ingredient's causing

depression or stimulation of cutaneous sensory receptors. In the skin protectant rulemaking (published elsewhere in this issue of the *Federal Register*), the agency is addressing claims for the treatment of symptoms of fever blisters and cold sores when the mechanism of action for these claims involves the ingredient's ability to provide a mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli.

In the *Federal Register* of February 8, 1983 (48 FR 5852), the agency published a tentative final monograph (proposed rule) for OTC external analgesic drug products, but it did not address products labeled for the treatment of cold sores and fever blisters. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations.

Interested persons were invited to submit comments by April 11, 1983, new data by February 4, 1984, and comments on new data by April 9, 1984. In response to that notice, a number of comments were submitted, but none of them concerned the specific use of external analgesic ingredients for the treatment of fever blisters and cold sores.

In this notice of proposed rulemaking, FDA responds to public comment and further discusses its position on OTC external analgesic drug products for the treatment of fever blisters and cold sores. Final agency action on this matter will occur with the publication of a future date of a final rule relating to OTC external analgesic drug products for these conditions.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will not longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and

"nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the *Federal Register*. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the *Federal Register* on November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

1. One comment suggested that zinc sulfate as a 0.25 percent solution be considered for topical use as a Category I ingredient for the treatment of fever blisters. The comment noted that zinc sulfate was not contained in the marketed products submitted to the Miscellaneous External Panel, and as a result was not discussed. The comment

pointed out that the National Institutes of Health (NIH) funded basic research, the results of which were not published until 1975 and 1977, which proved that zinc sulfate inhibited the synthesis of viral deoxyribonucleic acid (DNA) in cells infected with *herpes simplex virus* (HSV) (Refs. 1 and 2). The comment cited additional research funded by NIH (Ref. 3) as proving the selective inhibitory effect of zinc ions on the *herpes simplex* viral DNA polymerase. The comment mentioned an article by deRoeth (Ref. 4) as supporting topical application of 0.5 percent zinc sulfate solution as a highly effective treatment of Herpetic Keratitis, and cited the Merck Index (Ref. 5) as showing that zinc sulfate has been used in a concentration range of 0.2 to 1 percent as an astringent or styptic. The comment cited Brody (Ref. 6) as showing excellent results when concentrations of zinc sulfate solution less than 0.25 percent were applied to recurrent herpes simplex of the skin and oral mucous membrane. The comment mentioned an abstract (Ref. 7) supportive of zinc sulfate used in a concentration range of 0.025 to 0.05 percent as a solution for *herpes simplex* of the skin. The comment also provided pictures (Ref. 8) of patients treated topically with 0.25 percent zinc sulfate solution on their herpetic lesions. The comment concluded that zinc sulfate 0.25 percent in solution applied topically is safe, has been used to treat well over 100 patients without resultant skin irritation, and that a rapid drying and crusting of fever blisters results from its astringent activity.

The agency has reviewed the data submitted by the comment and determined that they are insufficient to classify zinc sulfate in Category I for the treatment of fever blisters. The submitted data show that zinc sulfate solution in a 0.2 to 1 percent concentration range applied topically produces an astringent effect on mucous membrane; however, the data are insufficient to demonstrate that zinc sulfate's astringent action is effective in the treatment of fever blisters. The studies (Refs. 1, 2, and 3) supportive of zinc inhibiting the synthesis of viral DNA in cells infected with HSV are in-vitro studies. Clinically-controlled in-vivo studies are needed to demonstrate that zinc sulfate causes a rapid drying and crusting of fever blisters. The effectiveness of 0.5 percent zinc sulfate solution against *herpes simplex* keratitis on the cornea (Ref. 4) is supportive, but is not a sufficient basis to extrapolate its effectiveness to the treatment of fever blisters in and around the mouth

because the skin around the mouth and the mucous membrane inside the mouth differ from the surface of the substance composing the cornea.

Brody (Ref. 6) studied 30 subjects with recurrent herpes simplex and post herpetic erythema multiforme who applied low concentrations (0.025 to 0.05 percent) of zinc sulfate solution 6 to 8 times a day to determine whether the solution would prevent relapse of the post-herpetic erythema multiforme. The results show that relapse was prevented without irritancy to the skin or mucous membranes; however, that success does not demonstrate the effectiveness of zinc sulfate in treating fever blisters. The abstract by Rees (Ref. 7) describes his use of a topical zinc solution in the treatment of herpes, but does not give his impression of its results. It lacks sufficient details to be useful. The comment's submission of patient pictures (Ref. 8) is also insufficient to support Category I status for zinc sulfate for the treatment of fever blisters.

The agency notes that the Merck Index (Ref. 5) states that zinc sulfate 0.2 to 1 percent topical solutions are irritating to the skin and mucous membrane. In addition, Brody (Ref. 6) also cites the Merck Index (Ref. 5) and states that for the skin and oral mucous membrane, these concentrations (0.2 to 1 percent) are too strong and cause irritation and an unpleasant dryness. Brody used concentrations in the 0.01- to 0.05-percent range in his studies. An appropriate safe concentration for the use of zinc sulfate in treating fever blisters needs to be determined.

Based on the above, the agency tentatively concludes that zinc sulfate in the concentrations considered has not been demonstrated as generally recognized as safe and effective for the treatment of fever blisters. The agency is classifying zinc sulfate in Category III and invites the submission of additional data.

References

- (1) Gordon, Y., Y. Asher, and Y. Becker, "Irreversible Inhibition of Herpes Simplex Virus Replication in BSC-1 Cells by Zinc Ions," *Antimicrobial Agents and Chemotherapy*, 8:377-380, 1975.
- (2) Shlomai, J., et al., "Effect of Zinc Ions on the Synthesis of Herpes Simplex Virus DNA in Infected BSC-1 Cells," *Virology*, 66:330-335, 1975.
- (3) Fridlender, B., N. Chejanovsky, and Y. Becker, "Selective Inhibition of Herpes Simplex Virus, Type 1 DNA Polymerase by Zinc Ions," *Virology*, 84:551-554, 1978.
- (4) deRoeth, A., "Treatment of Herpetic Keratitis," *American Journal of Ophthalmology*, 56:729-731, 1963.
- (5) Stecher, P.G., editor, "The Merck Index," 8th Ed., Merck and Co., Rahway, NJ, p. 1130, 1968.

(6) Brody, I., "Topical treatment of recurrent herpes simplex and post-herpetic erythema multiforme with low concentrations of zinc sulphate solution," *British Journal of Dermatology*, 104:191-194, 1981.

(7) Rees, R.B., "Zinc Sulfate Topically for Herpes Simplex," *The Schoch Letter*, 31:35, 1981.

(8) Comment C00035, Exhibit F, Docket No. 78N-0301, Dockets Management Branch.

2. Two comments urged the agency to place tannic acid in Category I for use as an astringent in the treatment of fever blisters. One comment stated that the Panel decided not to review tannic acid as an astringent (47 FR 39412 at 39426), but instead reviewed it as an ingredient for use in the treatment of fever blisters because the only submission on tannic acid was for a product which is indicated in the treatment of fever blisters and cold sores (Ref. 1). The comment added that the Panel concluded that tannic acid was safe for OTC use for the treatment of fever blisters, but evidence of its effectiveness is inadequate (47 FR 39419). The comment cited the Panel (47 FR 39419) as recommending that human studies be conducted because the use of astringents may be a rational treatment in shortening the healing time of fever blisters. The comment also cited the Panel's statement that astringents are locally applied protein precipitants which have such a low cell penetrability that the action is essentially limited to the cell surface and the interstitial spaces (47 FR 39426). The comment contended that such action would clearly be rational in the treatment of a fever blister. The comment added that the drying action of an astringent would be rational because it would be useful in causing the blister to atrophy and would treat the sore if bleeding, cracking, or separation occurs. Noting the Panel's description of the complications of herpes blisters (47 FR 39419), the comment contended that the usefulness of an astringent in treating these possible complications is obvious under the Panel's own reasoning.

The comment argued that tannins are one of the principal types of astringents, that the Panel classified witch hazel in Category I for effectiveness as an astringent because of its tannin content (47 FR 39428), and thus tannic acid would be useful in drying the lesion caused by a fever blister or cold sore and would promote healing of the lesion. (The agency notes that although the term "tannin" is synonymous with "tannic acid," the official name "tannic acid" is being used in this document (Ref. 2).) The comment concluded that tannic acid is safe and effective for treating fever blister and does not

require confirmation through unnecessary clinical studies.

The second comment supported its request by citing the Panel's statements at 47 FR 39426 that the affected area in contact with an astringent becomes drier, contending that such action would thus permit a fever blister to atrophy. The comment contended that this action would indicate tannic acid's effectiveness when applied to small areas of the lips to treat fever blisters.

In the amendment to the tentative final monograph for OTC skin protectant drug products used for treatment of fever blisters and could sores published elsewhere in this issue of the Federal Register, the agency discusses the use of tannic acid in the topical treatment of the symptoms of fever blisters and classifies it in Category III for safety and effectiveness. FDA believes that astringent properties may be useful in the treatment of the symptoms of fever blisters. However, the agency is concerned with potential oral mucosal absorption because of the proximity to the mucosal membranes of the oral cavity. Also, the agency is concerned about potential toxicity from oral ingestion, especially when eating and drinking, because of possible frequent applications of the drug to the lip and oral cavity. The agency that no efficacy studies were provided, nor did the manufacturer provide data to demonstrate the effectiveness to tannic acid alone in relieving the symptoms of fever blisters and cold sores.

The agency is aware that the Miscellaneous External Panel classified witch hazel in Category I as an astringent in the advance notice of proposed rulemaking and reopening of the administrative record for OTC external analgesic drug products published in the Federal Register of September 7, 1982 (47 FR 39412). The agency does not agree with the comments that the Panel attributed the astringent action solely to the tannins in witch hazel. The Panel stated that the effectiveness of witch hazel may be attributed to not only tannins, but possibly to the volatile oils and alcohol content in witch hazel (47 FR 39412 at 39428).

Although the agency acknowledges the concept of astringent properties as possibly being beneficial in alleviating the symptoms of fever blisters and cold sores, the agency believes that clinical data are needed to substantiate the effectiveness of the use of astringents in relieving these symptoms. In addition, based on the statement in the Merck Manual that "desiccating agents such as alcohol * * * are thought to fractionate

the herpes simplex virus, thereby inviting resistant and mutagenic strains" (Ref. 3), the agency has concerns about the relationship between the mechanism of action of astringents to precipitate protein in cells and the possible effect of the drug on the *herpes simplex* virus that causes the fever blisters. Further, in its discussion of cold sore treatment, the *Handbook of Non-Prescription Drugs* (Ref. 4) states that cold sore lesions should be protected from drying and fissuring because the cracking of the lesions may render them more susceptible to secondary bacterial infection, may delay healing, and usually increases discomfort. The handbook recommends that products that are highly astringent be avoided.

The agency concludes that data are needed to demonstrate tannic acid is safe and effective in relieving the symptoms of fever blisters and cold sores. In addition, because fever blisters generally occur in or around the mouth, the frequency and duration of application and oral toxicity levels of tannic acid need to be determined. Thus, the agency is classifying tannic acid for this use in Category III for both safety and effectiveness.

References

- (1) OTC Volume 180012.
- (2) Griffiths, M.C., editor, "USAN and the USP Dictionary of Drug Names", United States Pharmacopoeial Convention, Inc., Rockville, MD p. 533, 1989.
- (3) Berkow, R., editor, "The Merck Manual", 15th Ed., Merck Sharp and Dohme Research Laboratories, Rahway, NJ, p. 2328, 1987.
- (4) Baker, A.B., and D.K. Helling, "Oral Health Products" in "Handbook of Non-prescription Drugs", 8th Ed., American Pharmaceutical Association and The National Professional Society of Pharmacists, Washington, p. 492, 1986.

3. One comment requested that the following claims be added to the external analgesic monograph: for the temporary relief of discomfort of cold sores, fever blisters, sun blisters, and herpes or herpes labialis lesions" and "for relief from the discomfort of cold sores (herpes), sun and fever blisters." The comment contended that "the initial exposure (or longer exposure, i.e., 'overexposure') to stronger sunlight is the precipitating factor or cause of a 'fever blister/cold sore.'" The comment stated that, under such conditions, the consumer usually refers to herpes lip lesions as "sun blisters" (which they do not confuse with the same-named "sun blisters" that may follow a sunburn). The comment added that its marketing experience indicates that sun exposure, as described above, is the major cause of herpes labialis. The comment

supported use of the terms "herpes" and "herpes labialis" in OTC labeling on the Miscellaneous External Panel's statement at 47 FR 39418 which reads,

"Fever blisters" and "cold sores" are common names for herpes simplex, an acute infectious disease caused by the * * * virus *Herpes simplex*, type 1 * * *. The usual site of the lesion is at the junction of the mucous membrane and skin of the lips or nose. Hence, the term *herpes labialis* is frequently used.

The comment concluded that the terms "sun blisters," "herpes," and "herpes labialis" are acceptable OTC labeling when reference is clearly understood to be to the lips as it is with cold sores and fever blisters.

A second comment requested that the claim "For the temporary relief of discomfort of cold sores and fever blisters," be added to the external analgesic monograph for Category I analgesic/anesthetic/antipruritic ingredients in proposed § 348.10(b) and for Category I combinations in proposed § 348.20(b). The comment contended that part of the Panel's discussion of the treatment of fever blisters at 47 FR 39420 that "local anesthetics can relieve pain * * *" supports its request.

Prior to the publication of the external analgesic tentative final monograph (February 8, 1983; 48 FR 5852), the comment also requested that § 348.50(b)(2) of that tentative final monograph be amended to include fever blisters and cold sores, to read as follows, "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, fever blisters, cold sores, and minor skin irritations." The comment also cited support from the Miscellaneous External Panel's statement at 47 FR 39420 that "local anesthetics can relieve pain * * *" as that statement related to fever blisters.

The agency disagrees with the first comment's position that the terms "sun blisters," "herpes," and "herpes labialis" are acceptable OTC labeling for the indications in this rulemaking. The agency believes that the term "sun blisters" could be misleading and that consumers may confuse the term with the condition associated with excessive sunburn. In addition, the comment did not present any data to demonstrate that consumers usually refer to herpes lip lesions as "sun blisters," and the agency is not aware of any such data.

The term "herpes" is too broad and may be misleading to the consumer who may associate the term with the genital form of herpes. Further, the term "herpes labialis" is not a term that is familiar to the general public. In addition, the agency has concerns that consumers

may also confuse that term with the genital herpes condition. The Panel stated that the term "herpes labialis" is frequently used (47 FR 39412 at 39418), but did not indicate that the term was one that was common to the general public. The agency notes that the Panel did refer to "fever blisters" and "cold sores" as common names for herpes simplex. The agency believes that the terms "fever blisters" and "cold sores" are more readily recognized by the consumer and proposes that those terms be used in OTC drug product labeling.

In its discussion at 47 FR 39418, the Panel did not make any recommendations as to the Category I external analgesic ingredients considered to be safe and effective in the treatment of fever blisters. However, the Panel stated at 47 FR 39419 that recurrent herpes usually begins with a sensation of mild burning or itching and referred to a study where the researchers stated that the chief complaint from the subjects with fever blisters is pain. The Merck Manual describes fever blisters as "acute, painful vestibular eruptions of the oral mucosa or vermilion border * * *" and states that recurrent conditions begin with sensations of fullness, burning, and itching (Ref. 1). The agency believes that the comment's proposed claim "For the temporary relief of discomfort of cold sores and fever blisters" is too vague and does not inform the consumer of the specific symptoms to be relieved (i.e., pain and itching). Because the primary symptoms of fever blisters and cold sores are pain and itching, the agency agrees with the second comment and considers the proposed indication in § 348.50(b)(2), which states "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching") * * * to be more appropriate for fever blisters. The agency is proposing to add § 348.50(b)(5) to include a paragraph for products containing any external analgesic active ingredient identified in § 348.10 (a) and (b) to read as follows: "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "fever blisters," or "cold sores," or "fever blisters and cold sores"))).

Reference

- (1) Berkow, R. editor, "The Merck Manual," 15th Ed., Merck, Sharp and Dohme Research Laboratories, Rahway, NJ, p. 2327, 1987.

4. One comment requested that the following indication be added to the tentative final monograph on external

analgesic drug products for ingredients in proposed § 348.50(b) and combinations in proposed § 348.20: "Softens crusts (scabs) associated with cold sores and fever blisters." The comment contended that the claim conveys to the consumer the action of a product intended for this use and therefore should be acceptable OTC labeling. In support of its request, the comment cited the Miscellaneous External Panel's statement on OTC drug products for the treatment of fever blisters (47 FR 39412 at 39420):

Although most viral infections cannot be cured by OTC drugs, fever blisters should not be neglected. Local anesthetics can relieve pain, antibiotics can control secondary bacterial infections when they occur, and ointments (protectants) can soften crusts * * *. Drying agents such as alcohols, astringents, or skin protectant agents may be useful.

The agency notes that in the above statement the Panel said that local anesthetics are used to relieve pain and that ointments (protectants) can soften crusts. The comment did not present, and the agency is not aware of, any data that demonstrate that external analgesic ingredients soften crusts (scabs) associated with cold sores and fever blisters. Therefore, this claim will not be added to the external analgesic monograph. The use of skin protectant ingredients to soften crusts (scabs) associated with cold sores and fever blisters is discussed in comment 2 of the tentative final monograph for OTC skin protectant drug products for the treatment of fever blister and cold sores, published elsewhere in this issue of the *Federal Register*.

5. One comment suggested that the combination policy proposed in § 348.20(c) be amended to allow a combination of an external analgesic and a sunscreen for treatment and prevention of fever blisters and cold sores. The comment contended that any generally recognized safe and effective sunscreen is useful in the prevention and treatment of cold sores and fever blisters. Noting that the combination of an external analgesic and a sunscreen has been proposed as a Category II combination in the external analgesic rulemaking (December 4, 1979; 44 FR 69768 at 69790), the comment contended that for limited use on the lips, cold sores, and fever blisters, the combination should be placed in Category I.

The comment added that the usefulness of a sunscreen agent in preventing these blisters and lesions is evident from the Miscellaneous External Panel's own reasoning. The comment cited the Panel's statement that "such

events as fever, chilling, sunburn, windburn, menstruation, upset stomach or gastrointestinal disturbance, emotional stress or excitement may reduce the immune state sufficiently for the virus to become activated and again cause an infection, designated recurrent herpes" (47 FR 39412 at 39419). The comment also cited the report on Orally Administered Drug Products for the Treatment of Fever Blisters for OTC Human Use by the Advisory Review Panel on OTC Miscellaneous Internal Drug Products in which the Panel stated that exposure to sunlight could cause recurrent herpes (January 5, 1982; 47 FR 504).

The comment further contended that persons prone to "sun blisters" should avoid undue exposure to sunlight in the ultraviolet light range, which is thought to be the precipitating factor; namely, 290 nanometers up to and through the visible light wavelengths. The comment stated that this excess exposure can be reduced with the use of effective topical sunscreens.

The comment argued that products containing combinations of Category I external analgesic and sunscreen ingredients should thus be recognized as safe and effective for the prevention and relief of discomfort of fever blisters, sun blisters, and cold sores (herpes). While the comment acknowledged that the combination of an external analgesic and a sunscreen for use over the majority of the body may be irrational for the reasons discussed by the Topical Analgesic Panel, it contended that for the limited use on the lips, cold sores, and fever blisters the combination is not only rational but medically prudent. The comment added that this combination would meet the Topical Analgesic Panel's general combination policy (44 FR 69768 at 69785), which states:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The comment claimed that it has marketing experience to support the claim that effective protection from the sun can help prevent sun-induced herpes or lip "sun blisters."

The comment urged that § 348.20(c) be amended to include a paragraph to the effect that:

The active ingredients of the combination product consist of any single active ingredient identified in either (b)(1)(i), (b)(1)(ii), or (b)(2) of this section, or any combination identified in paragraph (b) of this section, and any generally recognized safe and effective sunscreen active ingredient provided the product is labeled for the concurrent symptoms involved, e.g., "For the temporary relief of pain and itching due to fever blisters, cold sores, canker sores, and other mouth sores and to help prevent the development or recurrence of these blisters and sores."

The comment requested the following indications for the external analgesic-sunscreen combination product: "Protects and helps prevent sun and fever blisters caused by overexposure to the sun," and "Filters (or screens or blocks [if applicable]) out the sun's rays to help prevent (lip) sun blisters." The comment contended that these claims convey the action of the drug product to the consumer and should be acceptable OTC labeling.

The agency acknowledges the statements made by the Miscellaneous Internal Panel and by the Miscellaneous External Panel concerning the effect of sunlight on causing recurrent herpes. However, those statements are not substantiated by supportive data that show that the use of a sunscreen will either treat or prevent fever blisters or cold sores. The agency's combination policy requires that each ingredient in the product make a contribution to the product's claimed effect. Data from clinical studies are needed to demonstrate that a combination product containing an external analgesic ingredient and a sunscreen ingredient is needed for concurrent administration and to support the role of the sunscreen ingredient, which appears to be prevention, while the external analgesic ingredient is relieving discomfort. The agency is classifying the combination of an external analgesic and a sunscreen ingredient in Category III, and invites the submission of data in support of the comment's contention that sunlight causes "sun blisters," and that a sunscreen will prevent their recurrence. Data are also needed to demonstrate that a target population exists which can benefit from concurrent use of the two types of ingredients in the same product. The claims requested by the comment will be considered when adequate supporting data for the combination product have been submitted.

6. One comment urged the agency to allow a combination of a Category I external analgesic, topical antimicrobial, and astringent for the treatment of fever blisters and cold sores. The comment contended that because treatment of

pain, prevention of infection, and the drying action of an astringent are all useful in the treatment of fever blisters and cold sores (as mentioned by the Miscellaneous External Panel at 47 FR 39420), the combination of these 3 types of ingredients should be placed in Category I. In support of its contention, the comment cited the combination policy set forth in the advance notice of proposed rulemaking for OTC external analgesic drug products (44 FR 69768 at 69785) which states that an OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population. The comment quoted the Topical Analgesic Panel's statements at 44 FR 69785 and underlined one part as follows:

The panel not only concurs with, but strongly supports this regulation, and believes that each active ingredient in a combination product must contribute to the claimed effect, and that the combination must provide rational concurrent therapy. It is the view of the Panel that it is irrational to use a combination product unless each of its active ingredients contributes to the effective treatment of at least one of the labeled symptoms for which the combination of ingredients is recommended. The specific combination should be at least as safe and effective as therapeutic doses of the individual active ingredients when used alone.

The comment noted that the Topical Analgesic Panel had recommended a combination of an external analgesic and a topical antimicrobial as a Category I combination in § 348.20(c)(2) at 44 FR 69865. The comment added that the three-ingredient combination that it was requesting would be a rational combination based on the external analgesic rulemaking and 21 CFR 300.50. Accordingly, the comment urged that proposed § 348.20(c) be amended to include a paragraph to the effect that:

The active ingredients of the combination product consist of any single active ingredient identified in either (b)(1)(i), (b)(1)(ii), or (b)(2) of this section, or any combination identified in paragraph (b) of this section, and any generally recognized safe and effective topical antimicrobial active ingredient or topical antimicrobial combination, and any generally recognized safe and effective topical astringent ingredient, provided the product is labeled for

the concurrent symptoms involved, e.g., for the temporary relief of pain and itching due to fever blisters, cold sores, canker sores, and other mouth sores and to promote healing and to protect against contamination of the sore.

In the tentative final monograph for OTC external analgesic drug products, the agency proposed that a combination of an external analgesic active ingredient in § 348.10 (a), (b), or (c) with a topical antimicrobial active ingredient or topical antimicrobial combination be Category I (48 FR 5852 at 5868). In this tentative final monograph, the agency is not proposing a combination of an external analgesic active ingredient identified in § 348.10 (a), (b), or (c) and any generally recognized safe and effective topical antimicrobial active ingredient or topical antimicrobial combination for the treatment of cold sores and fever blisters. In the notice of proposed rulemaking for OTC skin protectant drug products for the treatment of fever blisters and cold sores appearing elsewhere in this issue of the Federal Register, the agency explained in comment 3 that it lacks sufficient data to demonstrate the effectiveness of antimicrobial ingredients against fever blisters and cold sores. Accordingly, the agency classified in Category III for the treatment of fever blisters or cold sores any combination of a Category I skin protectant active ingredient in proposed § 347.10 (a) and (b) and a Category I antimicrobial active ingredient identified in part 333, subpart A. Similarly, because of the lack of data on claims for promoting healing and protecting against contamination of the sore, the agency is classifying in Category III any combination of an external analgesic active ingredient in proposed § 348.10 (a) and (b) and a Category I antimicrobial active ingredient or topical antimicrobial combination identified in part 333, subpart A. The agency invites the submission of data in support of any such combinations in treating fever blisters and cold sores.

Additionally, the safety and effectiveness of a combination of these two types of ingredients with an astringent has not been established, as the comment suggests. The agency is not aware of any data showing that an astringent would add anything to the combination. The benefit of adding an astringent to the combination of an external analgesic and an antimicrobial needs to be established. Therefore, at this time, the agency is also classifying the combination of an external analgesic, a topical antimicrobial, and an astringent in Category III.

7. One comment requested that § 348.20 of the tentative final monograph on OTC external analgesic drug products be amended to include a combination of a Category I astringent and an external analgesic ingredient provided that such products are appropriately labeled for both classes of ingredients. The comment contended that the Panel was aware that OTC ingredients are used on lesions amenable to treatment by external analgesics and astringents.

In the advance notice of proposed rulemaking for OTC astringent drug products, published in the Federal Register of September 7, 1982 (47 FR 39412), the Miscellaneous External Panel stated that it concurred with the FDA guidelines for OTC combination products which state that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC combination policy in all other respects (see 47 FR 39430). Although the Panel was aware of OTC drug products which combine various ingredients with an astringent (47 FR 39429), the Panel did not recommend any such combinations nor did it specifically mention combinations of an external analgesic with an astringent.

In the tentative final monograph for OTC astringent drug products that amends the tentative final monograph for OTC skin protectant drug products (54 FR 13490), the agency stated that it had surveyed the OTC drug marketplace and determined that such combinations are currently being marketed with claims such as for the temporary relief of itching or for anal/perianal itching and discomfort. Combinations of an external analgesic and an astringent were proposed as Category I for these uses in the tentative final monograph for OTC anorectal drug products, published in the Federal Register of August 15, 1988 (53 FR 30756).

In response to the comment's request to include the combination of an external analgesic and an astringent in the tentative final monograph for OTC external analgesic drug products, the agency has surveyed the OTC drug marketplace to determine if such products exist for use in the treatment of fever blisters and cold sores. The agency has identified some product containing a combination of several active ingredients that include an external analgesic and an astringent (Refs. 1 and 2). However, none of these products contain only an external analgesic and

an astringent. The comment did not provide information on any specific products to containing an external analgesic and an astringent, on the symptoms/conditions to be treated concurrently, or on the proposed labeling for such combinations. Further, the comment did not submit any data to support the combination of an external analgesic and an astringent in relieving the symptoms of fever blisters and cold sores.

The agency has questioned the safety and effectiveness of astringents in alleviating the symptoms of fever blisters (see comment 2 above), and has classified the use of an astringent in treating the symptoms of fever blisters and cold sores in Category III at this time. (See comment 6 in the amended tentative final monograph on OTC skin protectant drug products published elsewhere in this issue of the **Federal Register**.) Based on the above, the agency is classifying a combination of an external analgesic and an astringent ingredient for use in the topical treatment of the symptoms of fever blisters and cold sores in Category III.

References

- (1) Physicians' Desk Reference for Non-prescription Drugs, 8th Ed., Medical Economics Co., Inc., Oradell, NJ, p. 547, 1987.
- (2) Baker, A.B., and D.K. Helling, "Oral Health Products" in "Handbook of Non-prescription Drugs," 8th Ed., American Pharmaceutical Association and The National Professional Society of Pharmacists, Washington, p. 505, 1986.

II. The Agency's Evaluation of the Submissions

The Miscellaneous External Panel discussed only in general the use of OTC drug products for the treatment of fever blisters and cold sores. The Panel recommended that the agency consider in appropriate rulemakings ingredients and labeling claims submitted for treating fever blisters, cold sores, and their related symptoms (47 FR 39412 at 39418).

In this document, the agency discusses the use of OTC external analgesic drug products for the treatment of fever blisters and cold sores. The agency has evaluated eight submissions (Ref. 1) that were not reviewed by the Panel. Two manufacturers have requested that their submission (Refs. 2 through 8) be withdrawn from further consideration for all claims (Refs. 9 and 10). One manufacturer's submission concerned drug products containing stabilized aloe vera gel for topical use for numerous indications, including the treatment of fever blisters (Refs. 2 through 7). The other manufacturer's submission

concerned a liquid product with several labeling claims, one of which was "helps relieve itching and irritation of cold sores." The product contained alcohol, boric acid, chlorobutanol, camphor, glycerin, oxyquinoline sulfate, phenol (liquefied), resorcinol, and salicylic acid (Ref. 8).

References

- (1) OTC Volumes 160008, 160096, 160136, 160197, 160208, 160218, 160225, and 160278.
- (2) OCT Volume 160252A.
- (3) OTC Volume 160252B.
- (4) OTC Volume 160273.
- (5) OCT Volume 160274.
- (6) OTC Volume 160422.
- (7) OCT Volume 160423.
- (8) OCT Volume 160059.
- (9) Letter from A. J. Davis, Aloe Vera of America, Inc., to W.E. Gilbertson, FDA, dated May 20, 1988, in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.
- (10) Letter from S. Smith, Dep Corporation, to W.E. Gilbertson, FDA, dated May 3, 1988, in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.

8. One comment requested that two products, a surgical dressing and a cream containing a complexed mixture of camphor and metacresol in a 3:1 weight ratio, be classified in Category I as a local topical anesthetic for the relief of fever blisters. The comment contended that results of numerous studies and clinical tests submitted to other advisory review panels (Ref. 1) showed that the complex has a strong desensitizing and topical anesthetizing effect. The comment added that its two products have been marketed for almost 50 years, that its customers are primarily health-care professionals, and that there have been virtually no negative comments (adverse reactions and/or lack of effectiveness) on the products. The comment provided labeling for the two products; however, no claim for treatment of fever blisters appears on the submitted labeling.

Camphorated metacresol has been extensively reviewed in the external analgesic rulemaking and was proposed as a Category I ingredient for topical use in the tentative final monograph on OTC external analgesic drug products (48 FR 5852; February 8, 1983). The agency has considered which previously proposed Category I external analgesic ingredients would be appropriate to use on cold sores and fever blisters and is proposing camphorated metacresol as Category I for relief of pain and/or itch of cold sores or fever blisters in this tentative final monograph. (See discussion in comment 14 below.)

Reference

- (1) OTC Volume 160225.

9. A manufacturer submitted data (Refs. 1, 2, and 3) to the Miscellaneous External Panel on two products (a liquid and a powder dosage form) containing a complex formed by combining camphor with phenol. The labeling for the liquid product contains an indication, "relieves discomforts, helps to heal * * * fever blisters, cold sores * * *" among other indications. The powder product is labeled under the heading "For dry dressings and prickly heat." "For * * * cold sores, fever blisters * * *" among other indications. The liquid product contains camphor 10.8 percent complexed with phenol 4.7 percent in a light mineral oil vehicle. The powder product contains camphor 4.4 percent combined with phenol 2 percent.

Camphor 10.8 percent complexed with phenol 4.7 percent in a light mineral oil, U.S.P. vehicle has been extensively reviewed in the external analgesic rulemaking and was proposed as a Category I ingredient for topical use in the tentative final monograph on OTC external analgesic drug products (48 FR 5852; February 8, 1983). The agency has considered which previously proposed Category I external analgesic ingredients would be appropriate to use on cold sores and fever blisters and is including camphor 10.8 percent complexed with phenol 4.7 percent in a light mineral oil, U.S.P. vehicle for relief of pain and/or itch of cold sores or fever blisters in this tentative final monograph. (See discussion in comment 14 below.)

The agency notes that no information was provided to show that the camphor and phenol are present in a complex in the powder product. If a complex does not exist, the 2-percent concentration of phenol in the powder exceeds the 1.5-percent maximum concentration of phenol that was proposed as Category I in the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5867). In addition, camphor at 4.4 percent exceeds the 3 percent maximum concentration as an individual ingredient for analgesic, anesthetic, and antipruritic use proposed in the tentative final monograph for OTC external analgesic drug products (48 FR 5867). Further, it is not clear how the powder product would be used as a dry dressing (as stated in its labeling) on cold sores and fever blisters. Finally, the agency is aware that the powder product has not been marketed for a number of years (Ref. 4). Based on the above, the agency is classifying camphor 4.4 percent and phenol 2 percent as a powder for external analgesic use on fever blisters and cold sores in Category II.

References

- (1) OTC Volume 160136.
- (2) OTC Volume 160208.
- (3) OTC Volume 160218.
- (4) Memorandum of telephone conversation, June 8, 1989, between K. Bucko, Sterling Winthrop Co., and M.T. Benson, FDA, in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.

10. One manufacturer submitted data (Ref. 1) to the Miscellaneous External Panel for a combination product containing 6.37 percent benzocaine, 0.45 percent phenol, and 0.15 percent iodine with several labeling claims, one of which was for the temporary relief of discomfort of fever blisters and cold sores. According to the manufacturer, benzocaine was included in the product for its properties as a topical anesthetic to relieve pain attributed to cold sores and fever blisters, and the phenol and iodine were included as antiseptic agents. The submission included the results of animal studies to determine dermal and gingival toxicity in rabbits, literature references containing human safety data, and other literature references containing efficacy data. Subsequently, the manufacturer submitted updated labeling (Ref. 2) showing that the active ingredients of the product are benzocaine 6.3 percent, phenol 0.5 percent, and alcohol 70 percent. The manufacturer stated that the product had been reformulated since the original submission was made in 1978, and iodine is now an inactive ingredient. Subsequently, the manufacturer informed the agency that the product contains povidone iodine 0.48 percent stabilized with potassium iodide 1 percent to give 0.05 percent available iodine, with a labeled quantity of 0.04 percent to cover loss in manufacturer (Ref. 3). The manufacturer stated that iodine is included as a flavorant.

The ingredients contained in the currently marketed product when applied to the oral mucosa were reviewed and evaluated by the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (Dental Panel) in its report on OTC drug products for the relief of oral discomfort (May 25, 1982; 47 FR 22712), and by the Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel) in its report on OTC oral health care drug products (May 25, 1982; 47 FR 22760). Both panels classified benzocaine as an oral mucosal analgesic and as an anesthetic/analgesic in Category I in a 5- to 20- percent concentration range. The Dental Panel classified phenol as an oral mucosal analgesic in Category I in a 0.25- to 1.5- percent concentration range. The Oral

Cavity Panel classified phenol as an anesthetic/analgesic in Category I in a 0.5- to 1.5- percent concentration range and classified both phenol 0.5 to 1.5 percent and alcohol 70 percent in Category III as an antimicrobial in the mouth. The Oral Cavity Panel stated that commercially available mouthwashes contain ethanol as a solvent in concentrations up to 35 percent, but that concentrations above 35 percent cause burning of the mucous membranes (47 FR 22872). The Panel specifically stated that concentrations of ethanol that kill bacteria, e.g., 70 percent ethanol, cause burning and intense discomfort and are too irritating when applied to inflammations of the mucous membranes of the oral cavity (47 FR 22873). For the above reasons and because ethanol has marked potential for abuse, the Oral Cavity Panel recommended that the quantity of ethanol used as a solvent in pharmaceutical preparations should be limited to 35 percent.

In its report on OTC agents for the relief of oral discomfort (47 FR 22712 at 22737), the Dental Panel accepted the safety of 1.5 percent phenol in 70 percent ethanol for direct application to the gums for up to 7 days. The Panel concluded that up to 70 percent ethanol was an appropriate vehicle for 5 to 20 percent benzocaine with a maximum dosage of 1 milliliter and that the use of compound benzoin tincture (74 to 80 percent ethanol) and benzoin tincture (75 to 83 percent ethanol) was safe for occasional application to small areas of the oral mucosa regardless of the high alcohol content (47 FR 22747).

In its discussion of the effectiveness of ethanol as an antimicrobial agent (47 FR 22872), the Oral Cavity Panel pointed out that ethanol is ineffective as an antimicrobial ingredient at concentrations below 70 percent. However, that Panel also postulated that the lower concentrations of ethanol used as a solvent for an antimicrobial ingredient could act synergistically with the antimicrobial ingredient phenol, to produce an enhanced antimicrobial effect. The Panel then concluded that there were insufficient data from controlled studies to establish the effectiveness of ethanol alone as an antimicrobial agent and placed it in Category III.

In the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use published in the *Federal Register* of May 21, 1982 (47 FR 22324), the Miscellaneous External Panel stated that the "irritant action of alcohols is particularly marked on mucosa. The more concentrated the alcohol, the more pronounced are its

irritant effects" (47 FR 22327). The Panel recommended caution in the topical use of 60 to 95 percent ethanol and 50 to 91.3 percent isopropyl alcohol on the mucous membranes (47 FR 22327) and placed the indication "For application to mucous membranes" in Category II (47 FR 22332).

In the tentative final monograph for OTC oral health care drug products (January 27, 1988; 53 FR 2436), the agency proposed Category I classifications for benzocaine and phenol as anesthetic/analgesic ingredients, and provided that benzocaine and phenol may be combined in an anesthetic/analgesic product. The tentative final monograph, however, did not address the use of phenol or alcohol as an antimicrobial because the agency intends to address the use of antimicrobials in the mouth in a future issue of the *Federal Register*.

Based on the historical usage of iodine as an active ingredient, the agency questions whether a total iodine concentration of 0.04 percent can be considered an inactive ingredient. A final determination on the status of iodine has not been made in any OTC drug rulemaking.

In the proposed rule concerning inactive ingredients (42 FR 19156 at 19157), the agency stated the following:

Various OTC drug panels have questioned whether an OTC drug may retain as an inactive ingredient an ingredient that was formerly listed as an active ingredient, but which was found not to be generally recognized as safe and effective (Category II) or to require additional testing (Category III). If these ingredients have been promoted by manufacturers for an extended time, there is a potential for misleading consumers if the general recognition of the safety and effectiveness issue is unresolved and the name of the ingredient is retained on the label or in the labeling with an unwarranted degree of prominence. The Commissioner believes this should not be permitted, and this proposal is intended to preclude the retention and redesignation of an active ingredient as an inactive ingredient unless it serves an acceptable function as an inactive ingredient. As a result, manufacturers of OTC drug products containing an ingredient in Category II or Category III shall, at the end of the time period permitted for marketing, or if found to require further testing before a determination as to general recognition of safety and effectiveness can be made for such ingredients, be required by the effective date either to reformulate the product to remove the ingredient or if it is retained in the product as an inactive ingredient, to establish that the ingredient fulfills the requirements for use as an inactive ingredient in the product.

This proposal states that "flavors and flavoring adjuncts" are one of the

acceptable categories for inactive ingredients (42 FR 19160). The agency has no information that iodine is necessary as a flavor or flavoring adjunct, as defined in § 330.3(g) of the proposal, for use in OTC fever blister treatment drug products. The agency invites information and comments on (1) the use of iodine as a flavor or flavoring adjunct in OTC fever blister treatment and related drug products and (2) the minimum concentration of iodine needed to achieve a flavorant effect.

Notwithstanding the individual classifications of the active ingredients, the agency will require data to demonstrate safety and effectiveness of the combination of benzocaine, phenol, and alcohol (an anesthetic/analgesic and 2 antimicrobials (antiseptics) as described by the comment) on the oral mucosa for the temporary relief of cold sores and fever blisters. Therefore, the agency is classifying the combination of benzocaine, phenol, and alcohol in the above concentrations labeled for the treatment of cold sores and fever blisters in Category III.

References

(1) OTC Volume 160278.

(2) Letter from M. H. Davis, Whitehall Laboratories, to W. E. Gilbertson, FDA, dated June 27, 1988, in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.

(3) Letter from M. H. Davis, Whitehall Laboratories, to W. E. Gilbertson, FDA, dated January 27, 1989, in OTC Volume 06FBETFM, Dockets No. 78N-301F, Docket Management Branch.

11. A manufacturer submitted information to the Miscellaneous External Panel on a medicated core lip balm product containing an inner core and outer base. The active ingredients in the inner core were allantoin 0.2 percent and camphor 0.1 percent. The active ingredients in the outer base were escapol 506 0.75 percent, menthol 0.1 percent, allantoin 0.2 percent, and benzocaine 0.1 percent. The product labeling contained the claims, "Instant relief of chapped, dry lips," "Relieves pain, helps heal * * * fever blisters, cold sores, sun or windburned lips" and "Eases discomfort of cold sores, fever blisters and cracked lips due to sun or windburn." The submission contained letters attesting to no growth of various microorganisms in in-vitro testing, literature references on some of the labeled ingredients, testimonial letters in support of efficacy, an unsubstantiated opinion by a chemical consultant that the product contains ingredients useful for the safe and effective treatment of lip skin dyscrasia, and information on the sales in units of the product over 5 years.

Section 348.20(b) of the tentative final monograph on OTC external analgesic drug products, published in the *Federal Register* of February 8, 1983 (48 FR 5852 at 5868), provides for the combination of camphor 0.1 to 3 percent as an analgesic, anesthetic, and antipruritic ingredient and allantoin 0.5 to 2 percent as a skin protectant ingredient. It also provides for the combination of benzocaine 5 to 20 percent and menthol 0.1 to 1 percent as analgesic, anesthetic, and antipruritic ingredients, and allantoin 0.5 to 2 percent as a skin protectant ingredient. However, the tentative final monograph does not provide for a combination product containing all of these ingredients, and it does not provide for a product containing an inner core with some ingredients and an outer base with other ingredients. Further, the allantoin is present at a concentration less than the 0.5 percent minimum concentration proposed in the skin protectant tentative final monograph. Allantoin at this subtherapeutic concentration is Category III. In addition, the benzocaine is also present at a concentration less than the 5 to 20 percent minimum concentration proposed in the external analgesic tentative final monograph and thus is also Category III. Any Category III ingredients in a combination containing Category I ingredients render the combination Category III. Finally, there are no data showing how this inner core and outer base work, or on the need for different analgesic, anesthetic, and antipruritic ingredients in each area of the product. The agency is also aware that this product is no longer marketed (Ref. 1).

Escapol 506 is synonymous with padimate A, a Category I sunscreen ingredient at 1 to 5 percent. The submitted product contained 0.75 percent escapol 506, which would make it Category III. Combinations of sunscreen and external analgesic ingredients are discussed in comment 5 above.

The agency considers the claim "helps heal fever blisters and cold sores" to be a Category III skin protectant claim for wound healing agents based on the Topical Analgesic Panel's finding that no controlled studies have conclusively documented that skin protectant ingredients aid in wound healing (see 43 FR 34628 at 34647; August 4, 1978). The information submitted by the manufacturer did not include any safety and effectiveness data supportive of the use of the product for its labeled indications. In the absence of other in-vivo safety data, the letters attesting to no growth of various microorganisms in in-vitro testing are insufficient to

demonstrate the product's safety. Further, testimonial letters are not adequate to establish either product or ingredient effectiveness. Isolated reports, lacking details which permit objective scientific evaluation, cannot serve as the basis for establishing effectiveness. (See 21 CFR 330.10(a)(4)(ii).) The agency is therefore classifying the combination product as Category III, due to a lack of adequate data to establish safety and effectiveness.

Reference

(1) Memorandum of telephone conversations, June 9, 1988 and July 28, 1988, between H. Gordon, Commerce Drug, Inc., and M.T. Benson, FDA, in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.

12. One manufacturer submitted data to the Miscellaneous External Panel on a product containing a combination of 4 percent spirits of ammonia, 0.27 percent aqua ammonia, 0.4 percent phenol (90 percent), and 1 percent camphor in an ointment base and having the claim "quick relief for cold sores, fever blisters * * *" among other claims (Ref. 1). The submission included: (1) Acute oral toxicity studies, using the product on albino rats, in which the tester concluded that the product is nontoxic; (2) eye irritation study, on albino rabbits, in which the tester concluded that the product is not classified as an eye irritant in accordance with the Federal Hazardous Substances Act of September 17, 1964; and (3) a repeated insult patch test study, on 66 human subjects, in which the tester concluded that the product was nonirritating to any subject and showed no sensitization. The manufacturer indicated that sales exceeded 20,000,000 units in a 2-year period with no more than three complaints of an apparent allergic reaction. In support of efficacy, the manufacturer submitted a number of personal testimonials from several physicians and a number of consumers. The manufacturer contended that the long history and experience of the product may be considered substantiation in lieu of extensive scientific studies.

The Topical Analgesic Panel recommended that combination products containing Category I external analgesic active ingredients (topical analgesics/anesthetics/antipruritics) which depress cutaneous sensory receptors (e.g., camphor, phenol) combined with any Category I external analgesic (counterirritant) which stimulates cutaneous sensory receptors (e.g., strong ammonia water) be

classified as Category II because of the opposing pharmacological actions of each class (44 FR 69768 at 69787). Likewise, the agency did not allow such combinations of ingredients in the tentative final monograph for OTC external analgesic drug products (48 FR 5852). The agency notes also that the phenol concentration of 0.4 percent in the combination product is below the range of 0.5 to 1.5 percent proposed as safe and effective in the external analgesic tentative final monograph (48 FR 5852 at 5867).

With respect to the personal testimonials and extensive marketing history mentioned by the comment, these items alone cannot be regarded as adequate proof of safety or effectiveness without the corroboration of scientific data. Agency regulations provide that human experience during marketing may be used to support safety and to corroborate clinical effectiveness investigations but that isolated case reports, random experience reports, and reports lacking the details which permit scientific evaluation are not considered in establishing effectiveness. (See 21 CFR 330.10(a)(4)(i) and (ii).) The agency notes that the manufacturer did not provide any effectiveness data for its product. Based on this fact and the Topical Analgesic Panel's recommendations discussed above, the agency is classifying this combination product in Category II.

Reference

- (1) OTC Volume 160096.

13. One manufacturer submitted information to the Miscellaneous External Panel on a product containing 745.2 milligrams (mg) pectin per fluid ounce (oz) (approximately 2.5 percent) and 486 mg bismuth sodium tartrate per fluid oz (approximately 1.6 percent) and labeled for temporary relief of discomfort due to cold sores, fever blisters, and chapped lips (Ref. 1). The submission did not contain any data on the safety or effectiveness of the active ingredients. The manufacturer contended that the safety of the active ingredients has been well-documented in the literature and standard pharmacology texts. However, no citations were provided. Regarding effectiveness, the manufacturer stated that the bismuth salt has an astringent effect and may exert a mild antiseptic effect and thus prevent secondary infection, although no antimicrobial claims are made for the product. The manufacturer added that the bismuth salt also forms a smooth, protective coating which helps to keep the lesions dry, and the pectin in the product acts as

a demulcent. The manufacturer stated that the product is not a cure for cold sores and fever blisters, but it relieves discomfort, reduces irritation, and helps the self-healing process. The manufacturer concluded that safety has been substantiated by a long history of use without reports of adverse effects and no complaints that the product was ineffective.

As noted, the comment did not submit data on safety and effectiveness, and the agency has insufficient information to classify the ingredients bismuth sodium tartrate and pectin in Category I for relief of discomfort due to cold sores and fever blisters. Regarding safety, the agency takes cognizance of the manufacturer's statement that an average application of the product contains less than 2 mg of bismuth sodium tartrate and about 2.5 mg pectin, and that these amounts are far less than those ingested in antacid and antidiarrheal drug products. While some bismuth salts are included in the antacid monograph, bismuth sodium tartrate is not one of them. Further, no bismuth salts are currently classified in Category I as an antidiarrheal.

The agency notes that the Miscellaneous Internal Panel, in its report on OTC digestive aid drug products (January 5, 1982; 47 FR 454), reviewed the ingredient bismuth sodium tartrate and cited reports of bismuth encephalopathy from oral and topical use of products containing bismuth salts, including the pectate salt. The Panel reported that the implication is that the bismuth portion of the compound is toxic to the nervous system, although the mechanism involved is not clear. Based on that report, the agency has several safety concerns: (1) The bismuth sodium tartrate could react with pectin to form bismuth pectate, an implicated salt in causing bismuth encephalopathy, and (2) the product might be applied to sores on the mucous membrane, and thus provide for entry of the bismuth salt into the systemic circulation. Data are needed to show that these problems would not occur.

Regarding effectiveness, no clinical data were submitted to support any of the product's labeling claims. Clinical data are needed to demonstrate the effectiveness of the combination product and to show that each ingredient contributes to the claimed effects. In the absence of adequate safety and effectiveness data, the agency classifies the individual ingredients and the combination of bismuth sodium tartrate and pectin in Category III.

Reference

- (1) OTC Volume 160197.

14. The agency has evaluated all of the external analgesic active ingredients and combinations of active ingredients that were proposed as Category I in the tentative final monograph for OTC external analgesic drug products that was published in the Federal Register on February 8, 1983 (48 FR 5852 at 5867 to 5868) to determine which ones would be amenable to use for relieving the pain and itching of fever blisters and cold sores. The agency has determined that any of the ingredients listed in proposed § 348.10 (a) and (b) that depress cutaneous sensory receptors would be appropriate to use because of their analgesic, anesthetic, and antipruritic effects in relieving pain and itching of fever blisters and cold sores. These ingredients are classified in the tentative final monograph in § 348.10(a) as the "amine and caine"-type local anesthetics and in § 348.10(b) as the alcohols and ketones. However, the agency does not consider the Category I external analgesic antihistamine or hydrocortisone active ingredients in proposed § 348.10 (c) and (d) as appropriate for use on fever blisters or cold sores.

The agency has no basis to conclude that the action of an antihistamine in nullifying the effects of released histamine would relieve pain and itching of fever blister or cold sore lesions. In addition, no data have been submitted on products containing antihistamine ingredients for topical use for the treatment of fever blisters or cold sores, and the agency is not aware of such products historically being used for this purpose. Data are needed to demonstrate the safety and effectiveness of antihistamine ingredients for this topical use.

In the advance notice of proposed rulemaking for OTC external analgesic drug products, the Topical Analgesic Panel reviewed hydrocortisone preparations extensively but made no mention of the use of this ingredient on fever blisters or cold sores (44 FR 69768 at 69813 to 69824; December 4, 1979). The agency's current class labeling guideline for topical corticosteroids does not include the use of hydrocortisone on fever blisters or cold sores (Ref. 1). These guidelines state that topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Fever blisters and cold sores are not considered steroid-responsive dermatoses. The agency notes that the Miscellaneous External Panel, in its statement on OTC drug products for the treatment of fever blisters (47 FR 39412 at 39420), cited a

reference (Ref. 2) which stated that steroid hormone ointments are not recommended because they lessen defenses against infections and may spread the virus. The agency further notes that conflicting results have been reported when hydrocortisone was used against herpes. Ratner (Ref. 3) states that corticoids have not been found useful for treatment of *herpes simplex*. Robinson, Robinson, and Strahan (Ref. 4) state that subjects with *herpes simplex* did not show any response to treatment with hydrocortisone. Mullins and Hicks (Ref. 5) state that three cases of *herpes simplex* responded favorably to hydrocortisone within 24 hours. However, the concentration of the hydrocortisone acetate used was 2.5 percent, which is not an OTC concentration. Polano (Ref. 6) rated treatment with 1 percent hydrocortisone of one subject having *herpes simplex* as moderate. The agency finds these data too limited to establish that hydrocortisone is useful in treating fever blisters or cold sores. In addition, the agency is not aware of products containing hydrocortisone historically being used for this purpose. The agency concludes that additional data are needed to demonstrate the safety and effectiveness of hydrocortisone for this topical use.

The agency does not consider any of the counterirritant active ingredients proposed in § 348.12 as appropriate for use on fever blisters and cold sores because those ingredients stimulate rather than depress cutaneous sensory receptors. Thus, the mechanism of action of these ingredients is not desired for relief of pain or itch of fever blisters or cold sores.

Based on the above, the agency is proposing that the following ingredients be classified as Category I for use in relieving the pain and itching of fever blisters and cold sores at the following concentrations: Under § 348.10(a): (1) Benzocaine 5 to 20 percent, (2) butamben picrate 1 percent, (3) dibucaine 0.25 to 1 percent, (4) dibucaine hydrochloride 0.25 to 1 percent, (5) dimethisoquin hydrochloride 0.3 to 0.5 percent, (6) dyclonine hydrochloride 0.5 to 1 percent, (7) lidocaine 0.5 to 4 percent, (8) lidocaine hydrochloride 0.5 to 4 percent, (9) pramoxine hydrochloride 0.5 to 1 percent, (10) tetracaine 1 to 2 percent, and (11) tetracaine hydrochloride 1 to 2 percent. Under § 348.10(b): (1) Benzyl alcohol 10 to 33 percent, (2) camphor 0.1 to 3 percent, (3) camphor 3 to 10.8 percent when combined with phenol 4.7 percent, (4) camphorated metacresol (camphor 3 to 10.8 percent and metacresol 1 to 3.6

percent), (5) juniper tar 1 to 5 percent, (6) menthol 0.1 to 1 percent, (7) phenol 0.5 to 1.5 percent, (8) phenol 4.7 percent when combined with camphor in accordance with § 348.20(a)(4), (9) phenolate sodium 0.5 to 1.5 percent, and (10) resorcinol 0.5 to 3 percent.

Based on the above individual active ingredients being acceptable for this use, the agency is also proposing that the following combinations of external analgesic ingredients, with or without active ingredients from other classes, are appropriate for use in relieving pain and itching of fever blisters and cold sores:

- (1) Any ingredient identified in § 348.10(a) combined with any ingredient identified in § 348.10(b),
- (2) Any ingredient identified in § 348.10(b) (1), (5), (7), (9), and (10) combined with camphor and menthol identified in § 348.10(b) (2) and (6),
- (3) Camphor and phenol identified in § 348.10(b) (3) and (8) combined in a light mineral oil, U.S.P. vehicle,
- (4) Any ingredient identified in § 348.10 (a) or (b) or any combination identified in § 348.20(a) (1) or (3) combined with any generally recognized safe and effective skin protectant active ingredient or skin protectant combination identified in part 347 for treatment of fever blisters and cold sores provided the product is labeled for the concurrent symptoms.

References

- (1) Topical Corticosteroids Class Labeling Guideline, Food and Drug Administration in OTC Volume 06FBETFM, Docket No. 78N-301F, Dockets Management Branch.
- (2) "Canker Sores and Fever Blisters," National Institute of Dental Research, DHEW Publications No. [NIH] 79-247.
- (3) Ratner, H., "The Status of Corticosteroid Therapy in Dermatology," *California Medicine*, 83:331-335, 1955.
- (4) Robinson, Jr., H.M., R.C.V. Robinson, and J.F. Strahan, "Indications for Local Hydrocortisone Therapy," *Medical Times*, 83:227-237, 1955.
- (5) Mullins, J.F. and J.H. Hicks, "Hydrocortisone Ointment in the Treatment of Dermatologic Disorders," *Texas State Journal of Medicine*, 50:703-705, 1954.
- (6) Polano, M.K., "On the External Use of Hydrocortisone in Skin Diseases," *Acta Dermato-Venereologica*, 36:283-290, 1956.
- (7) Russell, B., et al., "A Valuation of Hydrocortisone Ointment," *The Lancet*, 268:1038-1043, 1955.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statements

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.*
The discussion below only applies to external analgesic drug products used

for the treatment of fever blisters and cold sores. Skin protectant drug products used for the treatment of symptoms of fever blisters and cold sores are discussed in the skin protectant rulemaking published elsewhere in this issue of the Federal Register.

Although the Miscellaneous External Panel mentioned the use of external analgesic ingredients for the treatment of fever blisters, it did not review or classify the individual ingredients. Most of the ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statement on OTC drug products for the treatment of fever blisters (47 FR 39412 at 39420). The Panel noted at 47 FR 39418 that many of these ingredients labeled with claims as external analgesic drug products for treatment of fever blisters have been previously addressed by other OTC advisory review panels. The agency is aware that many of these products were reviewed by the Topical Analgesic Panel.

The agency has further considered the Topical Analgesic Panel's recommendations on OTC external analgesic drug products (44 FR 69768), the tentative final monograph on OTC external analgesic drug products (48 FR 5852), and the additional data and information on tannic acid (see comment 2 above) and zinc sulfate (see comment 1 above).

Based upon the above discussion, the agency is adding two astringent active ingredients to the "Summary of Ingredient Categories" table for external analgesic active ingredients that appeared in the tentative final monograph for OTC external analgesic drug products (48 FR 5852). These additions involve ingredients used for the treatment of fever blisters and cold sores, i.e., tannic acid and zinc sulfate. An updated table appears below for the convenience of the reader.

SUMMARY OF INGREDIENT CATEGORIES

External analgesic active ingredients	Category
Analgesic, anesthetic, antipruritic active ingredients:	
Aspirin	III
Benzocaine	I
Benzyl alcohol	I
Butamben picrate	I
Camphor	I
Camphorated metacresol	I
Chloral hydrate	II
Chlorobutanol	III
Cyclomethycaine sulfate	III
Dibucaine	I
Dibucaine hydrochloride	I
Dimethisoquin hydrochloride	I

SUMMARY OF INGREDIENT CATEGORIES—
Continued

External analgesic active ingredients	Category
Diphenhydramine hydrochloride.....	I
Dyclonine hydrochloride.....	I
Eugenol.....	III
Glycol salicylate.....	III
Hexylresorcinol.....	III
Hydrocortisone ¹	III
Hydrocortisone acetate ¹	III
Juniper tar.....	I
Lidocaine.....	I
Lidocaine hydrochloride.....	I
Menthol.....	I
Methapyrilene hydrochloride.....	II
Phenol.....	I
Phenolate sodium.....	I
Pramoxine hydrochloride.....	I
Resorcinol.....	I
Salicylamide.....	III
Tetracaine.....	I
Tetracaine hydrochloride.....	I
Thymol.....	III
Trolamine salicylate ²	III
Triphenylamine hydrochloride.....	III
Counterirritant ingredients:	
Allyl isothiocyanate.....	III
Strong ammonia solution ³	III
Camphor.....	III
Capsaicin.....	III
Capsicum.....	III
Capsicum oleoresin.....	III
Chloral hydrate.....	III
Eucalyptus oil.....	III
Histamine dihydrochloride.....	III
Menthol.....	III
Methyl nicotinate.....	III
Methyl salicylate.....	III
Turpentine oil.....	III
Astringent ingredients:	
Tannic acid.....	III
Zinc sulfate.....	III
Other ingredients:	
Bismuth sodium tartrate.....	III
Pectin.....	III

¹ Hydrocortisone and hydrocortisone acetate are OTC external analgesics only for use as topical antipruritics.

² Identified by the Topical Analgesic Panel as triphenylamine salicylate.

³ Identified by the Topical Analgesic Panel as ammonia water, stronger.

In its statement, the Miscellaneous External Panel also listed a number of other ingredients that it said should be considered in other appropriate rulemakings for their use in treating fever blisters and cold sores, and their related symptoms (47 FR 39412 at 39418). The Panel recommended that the ingredients allantoin, glycerin, petrolatum, tannic acid, and white petrolatum for use on fever blisters be referred to the rulemaking on skin protectant ingredients and that other ingredients be referred to rulemakings which FDA considers appropriate. The agency notes that many of the ingredients listed by the Panel were intended as inactive ingredients, and they need not be reviewed as external analgesics for use on fever blisters. They are: ammonium carbonate, aromatic oily solution, beeswax, BHA, candelilla wax,

carnauba wax, castor oil, cetyl alcohol, lanolin, lanolin alcohol, mineral oil, octyldodecanol, ozokerite, paraffin, peppermint oil, petrolatum propyl/p-benzoate, sorbitan sesquioleate, soya sterol, spermaceti, titanium dioxide, wheat germ glycerides, and white petrolatum. One ingredient was listed under three names and was submitted as active and inactive, i.e., Escalol 506, amyl dimethyl p-aminobenzoate, and amyl para-dimethylaminobenzoate. That ingredient is also known as padimate-A, a Category I sunscreen ingredient, which together with homosalate has been deferred to the sunscreen rulemaking. Alcohol, calcium silicate, and talcum powder were not submitted to the Panel, although alcohol is being deferred to the rulemaking on OTC first-aid antiseptic drug products for use on cuts and wounds. Benzalkonium chloride is also being deferred to that rulemaking. Pyridoxine hydrochloride was deferred to the rulemaking on OTC skin protectant drug products. The following active ingredients have been considered in this rulemaking: ammonia, benzocaine, bismuth sodium tartrate, camphor, menthol, pectin, and phenol. The following ingredients were deferred to the oral cavity drug products rulemaking: anhydrous glycerol and carbamide peroxide.

2. *Testing of Category II and Category III conditions.* The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any external analgesic ingredient or conditions included in the review for the treatment of fever blisters and cold sores, by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the substance of the Miscellaneous External Panel's statements, including the Panel's description of what "fever blisters" and "cold sores" are. This Panel did not recommend a specific monograph for external analgesic drug products for use in the treatment of fever blisters and cold sores. However, the Topical Analgesic Panel did

recommend a monograph for external analgesic drug products (44 FR 69768), and the agency adopted this recommended monograph with some revisions in the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5867). The agency is amending that proposed monograph to include conditions for the treatment of fever blisters and cold sores based on its evaluations of the data and its responses to the comments described above, and the other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency is adding a definition for "fever blister, cold sore" in proposed § 348.3(h) as follows: "A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus *herpes simplex*, type 1."

2. The agency is proposing to add new paragraph (a)(4) to § 348.50 as an appropriate alternative statement of identity for external analgesic drug products used for the treatment of cold sores or fever blisters to read as follows: (4) *For products containing any ingredient in § 348.10 (a) or (b).* "Fever blister/cold sore treatment." The agency considers this proposed statement of identity to be descriptive and informative to consumers.

3. The agency is proposing to add new paragraph (b)(5) to read as follows:

(5) *For products containing any external analgesic active ingredients identified in § 348.10 (a) and (b).* "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching" (which may be followed by: "associated with" (select one or more of the following: "fever blisters," "cold sores," or "fever blisters and cold sores."))) (See comment 3 above.)

4. The agency is proposing that all of the active ingredients included in § 348.10 (a) and (b) of the tentative final monograph for OTC external analgesic drug products be classified as Category I for use in relieving the pain and itching of fever blisters and cold sores. (See comment 14 above.)

5. The agency is classifying zinc sulfate in Category III as an external analgesic for the treatment of fever blisters and cold sores. (See comment 1 above.)

6. The agency is classifying tannic acid in Category III as an external analgesic for the treatment of fever blisters and cold sores. (See comment 2 above.)

7. The agency is proposing that certain combinations of external analgesic ingredients, with or without active

ingredients from other classes, are appropriate for use in relieving the pain and itching of fever blisters and cold sores. (See comment 14 above.) The agency is adding a corresponding section for the labeling of such combination products.

8. The Agency is classifying the combination of an external analgesic and a sunscreen in Category III. (See comment 5 above.)

9. The agency is classifying the combination of an external analgesic, antimicrobial, and astringent in Category III. (See comment 6 above.)

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the *Federal Register* of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC external analgesic drug products for the treatment of fever blisters and cold sores, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). The assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC external analgesic drug products for the treatment for fever blisters and cold sores is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC external analgesic drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by May 31, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic

impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before May 31, 1990, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before May 31, 1990 publication in the *Federal Register*. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the *Federal Register*.

Interested persons, on or before January 31, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before April 1, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the *Federal Register* of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC external analgesic drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on April 1, 1991. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final

monograph is published in the *Federal Register*, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 348

External analgesic drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in part 348 (as proposed in the *Federal Register* of February 8, 1983; 48 FR 5852) as follows:

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 348 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 348.3 is amended by adding new paragraph (h) to read as follows:

§ 348.3 Definitions.

(h) *Fever blister, cold sore*. A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus *herpes simplex*, type 1.

3. Section 348.20 is amended by adding new paragraph (b)(3) to read as follows:

§ 348.20 Permitted combinations of active ingredients.

(b) ***
(3) Any ingredient identified in § 348.10 (a) or (b) or any combination identified in § 348.20(a) (1) or (3) may be combined with any generally recognized safe and effective skin protectant active ingredient or skin protectant combination identified in part 347 of this chapter for treatment of fever blisters and cold sores provided the product is labeled according to § 348.52.

4. Section 348.50 is amended by adding new paragraph (a)(4), by redesignating paragraph (b)(5) as paragraph (b)(6), and by adding new paragraph (b)(5) to read as follows:

§ 348.50 Labeling of external analgesic drug products.

(a) ***
(4) For products containing any ingredient in § 348.10 (a) or (b). "Fever blister/cold sore treatment."
(b) ***
(5) For products containing any external analgesic active ingredients

identified in § 348.10 (a) and (b). "For the temporary relief of" (select one of the following: "Pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "fever blisters," "cold sores," or "fever blisters and cold sores"))).

* * * * *

5. Section 348.52 is added to read as follows:

§ 348.52 Labeling of permitted combinations.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as

established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in the applicable OTC drug monographs, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction

into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

Dated: December 25, 1989.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-2163 Filed 1-30-90; 8:45 am]

BILLING CODE 4160-01-M

The American Medical Association is a non-profit corporation organized for the purpose of promoting the interests of the medical profession and the public. It was founded in 1847 and has since that time been the leading organization of the medical profession in the United States. The Association is composed of more than 50,000 members, who are physicians, surgeons, dentists, and other medical practitioners. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

The Journal of the American Medical Association is a weekly publication that contains a wide variety of articles on medical topics. The articles are written by leading medical authorities and are of high quality. The Journal is published in English and is available to all members of the Association. The Journal's content is divided into several sections, including original articles, reviews, and news. The Journal is a valuable resource for all medical practitioners and is highly respected in the medical community. The Journal's circulation is over 100,000 copies per week. The Journal is published by the American Medical Association, which is a non-profit corporation. The Association's headquarters are in Chicago, Illinois. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

The American Medical Association is a non-profit corporation organized for the purpose of promoting the interests of the medical profession and the public. It was founded in 1847 and has since that time been the leading organization of the medical profession in the United States. The Association is composed of more than 50,000 members, who are physicians, surgeons, dentists, and other medical practitioners. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

The Journal of the American Medical Association is a weekly publication that contains a wide variety of articles on medical topics. The articles are written by leading medical authorities and are of high quality. The Journal is published in English and is available to all members of the Association. The Journal's content is divided into several sections, including original articles, reviews, and news. The Journal is a valuable resource for all medical practitioners and is highly respected in the medical community. The Journal's circulation is over 100,000 copies per week. The Journal is published by the American Medical Association, which is a non-profit corporation. The Association's headquarters are in Chicago, Illinois. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

The American Medical Association is a non-profit corporation organized for the purpose of promoting the interests of the medical profession and the public. It was founded in 1847 and has since that time been the leading organization of the medical profession in the United States. The Association is composed of more than 50,000 members, who are physicians, surgeons, dentists, and other medical practitioners. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

The Journal of the American Medical Association is a weekly publication that contains a wide variety of articles on medical topics. The articles are written by leading medical authorities and are of high quality. The Journal is published in English and is available to all members of the Association. The Journal's content is divided into several sections, including original articles, reviews, and news. The Journal is a valuable resource for all medical practitioners and is highly respected in the medical community. The Journal's circulation is over 100,000 copies per week. The Journal is published by the American Medical Association, which is a non-profit corporation. The Association's headquarters are in Chicago, Illinois. The Association's primary concern is the advancement of the medical profession and the improvement of the medical service to the public. It does this by publishing the Journal of the American Medical Association, which is one of the most important medical journals in the world. The Association also holds annual meetings and publishes a variety of other publications. The Association's headquarters are in Chicago, Illinois.

Reader Aids

Federal Register

Vol. 55, No. 21

Wednesday, January 31, 1990

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	523-5227
Public inspection desk	523-5215
Corrections to published documents	523-5237
Document drafting information	523-5237
Machine readable documents	523-3447

Code of Federal Regulations

Index, finding aids & general information	523-5227
Printing schedules	523-3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523-6641
Additional information	523-5230

Presidential Documents

Executive orders and proclamations	523-5230
Public Papers of the Presidents	523-5230
Weekly Compilation of Presidential Documents	523-5230

The United States Government Manual

General information	523-5230
---------------------	----------

Other Services

Data base and machine readable specifications	523-3408
Guide to Record Retention Requirements	523-3187
Legal staff	523-4534
Library	523-5240
Privacy Act Compilation	523-3187
Public Laws Update Service (PLUS)	523-6641
TDD for the deaf	523-5229

FEDERAL REGISTER PAGES AND DATES, JANUARY

1-128	2
129-242	3
243-418	4
419-590	5
591-708	8
709-838	9
839-990	10
991-1170	11
1171-1352	12
1353-1556	16
1557-1660	17
1661-1780	18
1781-2046	19
2047-2216	22
2217-2358	23
2359-2508	24
2509-2600	25
2601-2802	26
2803-3028	29
3029-3196	30
3197-3384	31

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

1 CFR	910..... 3, 728, 1173, 1790, 2803
305.....	1665
3 CFR	
Proclamations:	
6085.....	591
6086.....	593
6087.....	709
6088.....	991
6089.....	1661
6090.....	2217
Executive Orders:	
12543 (See Notice of Jan. 4, 1990).....	589
12544 (See Notice of Jan. 4, 1990).....	589
12699.....	835
12700.....	2219
Administrative Orders:	
Notices:	
Jan. 4, 1990.....	589
Presidential Determinations:	
No. 90-5 of Jan. 2, 1990.....	1663
No. 90-6 of Jan. 3, 1990.....	595
4 CFR	
25.....	2359
5 CFR	
534.....	1353
550.....	1353
581.....	1354
591.....	1370
841.....	993
870.....	993
871.....	993
872.....	993
873.....	993
890.....	993, 1781
1201.....	548
1655.....	978
2429.....	2509
2638.....	1665
Proposed Rules:	
315.....	2385
7 CFR	
1e.....	106
52.....	3029
58.....	2360
215.....	1376
225.....	1376
226.....	1376
235.....	1376
272.....	1670
275.....	1670
301.....	711, 712, 3037
354.....	2221, 3197
401.....	1782, 1784
456.....	1785
719.....	1557
793.....	1557
801.....	839
905.....	1786, 2222, 2223, 2601
907.....	1, 726, 839, 841, 1171, 1788, 2604
908.....	841
918.....	1379
955.....	715
967.....	2362
979.....	723
981.....	129
982.....	724
989.....	2224
1002.....	3198
1032.....	2226
1210.....	2047
1405.....	1557
1413.....	1557
1421.....	1557
1430.....	2363
1446.....	1383, 1385
1497.....	1557
1498.....	1557
1762.....	130, 2509
1772.....	1791
1786.....	1142
1900.....	1576
1942.....	134
1980.....	136, 2365
3402.....	2214
Proposed Rules:	
1.....	636
51.....	2383
401.....	1825
425.....	295
929.....	295
932.....	737
948.....	299
959.....	437
1250.....	3064
1786.....	1152
8 CFR	
208.....	2803
214.....	2606
238.....	1576
242.....	1576, 2803
286.....	729
Proposed Rules:	
212.....	438
214.....	438
238.....	438
9 CFR	
78.....	419, 3200
97.....	2227, 3197
381.....	145
Proposed Rules:	
310.....	2386
391.....	439
10 CFR	
2.....	843
10.....	4
19.....	243
34.....	843, 2281
73.....	3039
420.....	3000
430.....	996
455.....	3000
465.....	3000
Proposed Rules:	
35.....	1439
436.....	2590

11 CFR		91.....2206	801.....548	700.....78
100.....2281		327.....1215	Proposed Rules:	702.....78
102.....2281		15 CFR	10.....1471	750.....78
110.....1139, 2281		779.....3204	179.....646	870.....78
114.....2281		785.....3204	310.....797, 1471, 2202	905.....78
9034.....2281		799.....2281, 3204	314.....1471	910.....78
12 CFR		Proposed Rules:	320.....1471	912.....78
5.....996		400.....2760	333.....797, 2202	921.....78
32.....854		776.....3016, 3017	341.....310, 2367	922.....78
203.....695, 2481		16 CFR	343.....1471	925.....618
207.....2631		Proposed Rules:	347.....3362	933.....78
220.....2631		Chapter II.....3071	348.....3362	934.....1813
221.....2631		401.....878	369.....1471	935.....3219
224.....2631		414.....879, 1768	1020.....1472	937.....78
312.....1912		1700.....1456, 2733	22 CFR	939.....78
528.....1386		17 CFR	512.....3050	941.....78
563d.....3040		3.....3205	23 CFR	942.....78
571.....126, 696		4.....3205	655.....2373	947.....78
700.....1792		270.....1641	1313.....1185	Proposed Rules:
701.....1792, 1798		274.....959	24 CFR	16.....2212
705.....1792		279.....959	16.....2064	56.....2535
741.....1792, 1798		Proposed Rules:	103.....3209	57.....2535
910.....2228		155.....1047	201.....420, 1312	58.....2535
912.....2228		200.....1678	203.....280, 1312	70.....2535
931.....1393, 2228		230.....1460	234.....1312	71.....2535
932.....1393, 2228		239.....1460	291.....1156	72.....2535
933.....2228		270.....1460	577.....1156	75.....2204, 2535
934.....2228		274.....1460	578.....1156	90.....2535
935.....2228		18 CFR	579.....3170	218.....3232
936.....2228		16.....4	812.....3211	243.....158
937.....2228		37.....146, 2060	813.....3211	256.....2388
938.....2228		154.....1174	885.....3211	816.....2105
939.....2228		157.....1174	912.....3211	817.....2111
940.....2228		250.....1807	913.....3211	901.....647
941.....2228		260.....1174	Proposed Rules:	904.....2239
942.....2228		270.....20	50.....396, 2533	914.....2536, 2538, 3233
943.....2228		284.....1174	55.....396, 2533	917.....1216
944.....2228		385.....1174	58.....396, 2533	920.....2111
950.....2228		388.....1174	200.....396, 2533	935.....649
955.....2228		Proposed Rules:	25 CFR	938.....2675
Proposed Rules:		1312.....2848	Proposed Rules:	946.....2240
208.....582		19 CFR	262.....2580	948.....34
225.....582		12.....1809	26 CFR	31 CFR
602.....440		Proposed Rules:	1.....283, 729, 1406, 1768, 2374, 2511-2515, 3051, 3211	2.....1644
701.....1827		12.....1809	7.....1406	103.....1021
1505.....820		20 CFR	602.....1406, 2374, 3211	351.....566
13 CFR		12.....1809	Proposed Rules:	353.....575
116.....2048		24.....2386	1.....310, 739, 1215, 1472, 2100, 2534, 2535, 3231	515.....2644
120.....2049, 2050		111.....2528	7.....1472	32 CFR
121.....3201		113.....2528	602.....1472, 3231	40a.....23
122.....2050		133.....2386	27 CFR	154.....3223
14 CFR		134.....1837	5.....1768, 1912	199.....621
21.....270, 2366		142.....2528	9.....285	394.....2806
23.....270		143.....2528	Proposed Rules:	395.....2807
25.....2366		159.....2528	5.....1061	706.....152, 1418
39.....248-269, 597-607, 857-860, 998, 1006, 1400, 1401, 1579, 1799, 1805, 2051, 2056, 2231, 2634-2639, 3041-3047		357.....1348	28 CFR	842.....2909
71.....609, 610, 1402, 1535, 2059, 2060		21 CFR	0.....1583	Proposed Rules:
73.....274, 610, 1806		Ch. I.....276	2.....288, 289, 862	199.....2116, 3234
75.....611, 1403		14.....1404	545.....78	220.....1473
91.....412		19.....1404	29 CFR	229.....2848
95.....1008		20.....1404	503.....106	33 CFR
97.....274, 612, 1581, 3049		133.....2510	1601.....2518	100.....153, 1583
1221.....1404		176.....1672	1910.....3146, 3300	110.....154
1240.....613		430.....2640	1915.....3146	117.....2065, 3054
Proposed Rules:		440.....277, 278, 2481	1917.....3146	165.....27, 734, 1583, 1584, 2645
Ch. I.....2237		444.....616, 2642	1918.....3146	334.....2586, 3055
21.....2665		452.....279, 2481	1956.....1204	Proposed Rules:
25.....2665		455.....2640	2610.....1206	80.....2539
27.....988		510.....1405, 1673	2622.....1206	100.....3235
29.....698, 988		520.....2233, 3208	2644.....1208	110.....1679
39.....300-309, 877, 1043, 1046, 1450, 1451, 1831-1834, 2095-2098, 2237, 2667-2672, 3066, 3067		522.....1405	2676.....1208	34 CFR
71.....645, 1452-1454, 1544, 1836, 2095-2099, 2674, 2675, 3068-3070		556.....3208	Proposed Rules:	319.....194
75.....1455		558.....22, 1406	1910.....2101, 2776	669.....2772
			1926.....2101	755.....1584
			30 CFR	Proposed Rules:
			220.....1209	302.....1217

1220.....	1912
1222.....	1912
1224.....	1912
38 CFR	
4.....	154
Proposed Rules:	
1220.....	740
1222.....	740
1224.....	740
39 CFR	
111.....	3056
Proposed Rules:	
3001.....	3236
40 CFR	
52.....	735, 1052, 1419, 1420, 2066, 2234
60.....	28
61.....	28, 78
81.....	1420
180.....	1585, 2376-2379, 2833
186.....	1423
228.....	1024
260.....	2322
261.....	2322
262.....	2322
350.....	420
749.....	222
761.....	695
795.....	627
799.....	627, 3058
Proposed Rules:	
51.....	3237
52.....	311, 1592, 2245, 2390, 2842, 3073, 3237
60.....	3237
81.....	35
85.....	1680, 3073
86.....	1914, 2248
141.....	160
143.....	160
180.....	2391, 2844, 2845
185.....	2845
261.....	2248, 2847
372.....	650
435.....	2540
600.....	1680
41 CFR	
105-1.....	1673
105-2.....	1674
201-1.....	29
201-2.....	29
201-23.....	29
201-24.....	29
Ch. 301.....	1946
301-8.....	2379
302-11.....	1674
42 CFR	
100.....	2652
405.....	2652
411.....	1819
412.....	290, 1819
413.....	290, 2652
433.....	1423, 1820
447.....	1423, 2652
489.....	1819
43 CFR	
3470.....	2653
Proposed Rules:	
7.....	2848
3160.....	1837
Public Land Orders:	
6760.....	695
6761.....	862
6762.....	863
6763.....	1210
44 CFR	
64.....	155, 2834, 2836
65.....	2838, 2839
67.....	863, 2840
206.....	2284, 2297

334.....	1820
Proposed Rules:	
67.....	743, 1217, 1226, 2849
45 CFR	
3.....	2067
Proposed Rules:	
1180.....	1592
46 CFR	
15.....	1210
16.....	634
54.....	696
90.....	2522
91.....	2522
540.....	1823
550.....	3059
586.....	2071
Proposed Rules:	
30.....	2978
151.....	2978
153.....	2978
197.....	2978
540.....	1850
580.....	315
581.....	315
47 CFR	
0.....	1678
1.....	2380
73.....	290, 291, 421, 869, 1035, 2236, 2664
74.....	3062
Proposed Rules:	
0.....	315
1.....	315
2.....	315, 744
15.....	879, 2852
68.....	879
73.....	322-327, 881-885, 1065, 1066, 1481-1483, 2254, 3237-3240
76.....	1483, 1484
80.....	2392, 2393
87.....	2393
90.....	328, 744
94.....	3241
95.....	315
48 CFR	
3.....	3190
52.....	30, 3190
303.....	2077
525.....	421
Proposed Rules:	
9.....	416, 3174
16.....	2356
17.....	2356
19.....	2358
22.....	3174
23.....	3174
31.....	1554
33.....	990
36.....	3174
48.....	416
52.....	30, 2358, 3174
205.....	962
208.....	962, 1593, 1594
209.....	962
214.....	962
215.....	962
225.....	962
246.....	962
252.....	962, 1593, 1594
271.....	1594
522.....	445
552.....	445
970.....	2796
Appendix T.....	962
49 CFR	
171.....	422, 870
172.....	870
173.....	422, 870
175.....	870
199.....	797

571.....	1586, 1681
594.....	78
653.....	2526
1312.....	1035
1313.....	156
Proposed Rules:	
240.....	2395
392.....	37
567.....	747
571.....	446, 747, 760, 1226, 1681, 3242
572.....	1139
585.....	747
605.....	334
1151.....	1067
50 CFR	
17.....	425, 429
204.....	2201
229.....	2201
611.....	291, 1036, 1434, 1591, 3223, 3229
641.....	2078
642.....	1212
650.....	433, 2201
652.....	1213
663.....	30, 1036
672.....	31, 1036, 3223, 3230
675.....	31, 1036, 1486, 1434, 3229
Proposed Rules:	
16.....	1851
17.....	761, 886, 1230, 1486, 1488, 2541
228.....	1685, 3074
301.....	1491
628.....	652, 2853
642.....	2118
651.....	38, 1853
658.....	447

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List: January 19, 1990.

Order from Superintendent of Documents,
U.S. Government Printing Office,
Washington, DC 20402-9325.

S

a

1-

r

0

S

□

□

!

00

